

Episode 43: Value of metrics in the laboratory environment

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 explore how quality performance metrics are transforming clinical laboratory operations and why measuring the details from accuracy to turnaround times is essential for improving everything from test results to patient care. Metrics such as Six Sigma and other means of measurement are not simply numbers, they're powerful tools for uncovering performance gaps, improving processes and laboratory workflow, and ensuring the consistent high-quality diagnostic results that healthcare providers and patients depend on. Today we'll dive into the practical applications of metrics including how they help prepare labs for regulatory compliance, streamline operations and build confidence in diagnostic accuracy.

Joining us today is Johanna Miller, global product manager for QuidelOrtho. Johanna brings a wealth of expertise working with laboratory metrics. She also has a strong background in data science, and she recently published a peer-reviewed article on a novel approach to leveraging big data to calculate Sigma metrics using input from real-world clinical laboratories. Johanna has also worked closely with lab teams to build the discipline to provide metrics they can use to improve their performance. She's passionate about helping lab staff achieve excellence through data and innovation, and today she'll share her insights on how metrics can help teams navigate challenges, prioritize improvements and ultimately deliver the best possible outcomes for patients. Welcome, Johanna, thanks for joining us.

Johanna Miller: Yeah, thank you for having me.

Josh Casey: Well, we have a lot to cover and it's a subject our audience really wants to know more about, so let's jump right in. To set the stage for our discussion, can you talk a little bit about why quality metrics, not just the test results, are essential for clinical laboratories?

Johanna Miller: Sure, so quality metrics are helpful because they can provide you with a structured way to monitor and improve the performance of your lab. So, kind of starting with, first and foremost, they help you understand what your current state is. Once you know what your current state is and you have your metrics, you can then begin to ask questions like, where should I focus my effort? What changes can I explore to potentially improve these metrics? So, as you continue to collect and monitor your metrics, then they, after some time, they'll become something that saves you time, right? So, if you see a metrics change, right? So, if you see poor metrics one month, but you know for a fact that you were fine last month, well, then now you've got a narrow time window for your investigation, and that will save you lots of time. So, it's a matter of understanding where you stand. And it's up to the lab to determine which quality metrics work best and what the goals will be around those metrics. For example, it's very common to place metrics around QC results and monitor those metrics very closely. For example, precision in every single day monitoring that QC result and what that precision is. Other labs, you know, especially if you have multiple instruments, you can choose to have metrics around how similar instruments need to perform relative to each other. Other labs can choose to monitor how similar their test results are to other labs. So where you stand relative to your peers. Now for that last one, you know, whether you're actively monitoring or not or proactively monitoring it, you do get a periodic sense of where you stand when proficiency testing or external quality assurance testing occurs. You'll get that report back from your EQA program. So, in the U.S., the CLIA limits for proficiency testing, they've



recently been updated and in many cases tightened. So many labs are opting to get ahead of that by proactively monitoring and calculating Sigma metrics as a way to kind of understand where they stand relative to those new limits.

Josh Casey: Excellent, thank you, and you just mentioned Sigma, and I know we've heard a lot about Sigma metrics in the lab recently. Can you briefly talk about what it is and the methodology behind it?

Johanna Miller: Yeah, so Sigma metrics, they are, they are a particular or very specific metric that that's gaining in popularity. And so what the Sigma metrics is, it's a calculation that takes into account multiple metrics that a lab might be measuring or calculating already. For example, the precision of your QC, right? You'll have each assay, you'll have the precision. And without Sigma metrics, you would need to know whether there's a look-up table or just instinctively that, you know, 5% CV precision is very good for this assay but terrible for another, and trying to keep all that straight, right, so, you have your precision, and then the single metrics you combine your accuracy, which is how far you are from a true value. And then the third component is your allowable error. So, that's a limit, and the lab can choose the allowable error, but in many cases we would use, say for example, those new CLIA limits. And so by combining all three of those, right: the precision, the accuracy and the allowable error, those all plug into a calculation and then you get a number from 0 to 6, with 6 being the best and the higher the number, the better. And so by putting everything in that same scale, then you don't have to memorize, right, what the limits are for different things because it's all just plugged in the calculation.

Josh Casey: Great, so it sounds like it's a way of standardizing and having that consistency in the measurements and what teams are looking at.

Johanna Miller: Yeah, yeah, exactly. So, it's a way to sort of to standardize. So now you have, you're talking about the same scale and the same metric for all your assays, or all your quantitative assays I should say. So now you don't have to remember, right, what the expected performance is for each of them because it's kind of built into the calculation.

Josh Casey: OK, so, getting more into the application in the lab, when it comes to enhancing lab operations, what are some of the ways that metrics like Six Sigma play into that?

Johanna Miller: Sure, so when you calculate your Sigma metric, it becomes very powerful because now you have a single quality metric that's a numerical value for the quality of all of your assays, so you can kind of look and pinpoint performance gaps, prioritize improvements, because you're able to look at all of your assays on the same scale and then once you know, hey, this assay needs a little more attention, then you can target improvements so that you continuously become better. It becomes part of this, you know, many labs will choose to make a periodic review of their Sigma metrics and then target performance improvements. And what's really nice about Sigma metrics, so it makes them very helpful and why many labs like them is because they can be a predictor of your proficiency testing performance. So, typically what you would do is you would aim for a Sigma value of at least 3, and if you have a Sigma value of 3 or better, then you can have pretty high confidence that later, when you have a proficiency testing challenge, that statistically speaking, you're very likely to pass that challenge. And so if you calculate your Sigma metrics ahead of time, that kind of serves as a preview, and you can get ahead of any potential issues.



Josh Casey: Great, thank you for that. You mentioned performance gaps and related issues. What are some of the ways that metrics can help, you know, practically address some of those challenges?

Johanna Miller: So, I mean, metrics provide you with the insights that you can understand where to take action in very, very specific targeted areas. So for example, you can observe, you know, if you have poor Sigma metrics for particular as you can look to see, OK, should I recalibrate? Should I adjust workflows? So, it allows you to be proactive in that sense. There's also, you know, it can help highlight areas of environmental or handling issues, and through that, you can improve your QC reliability or that your QC precision. And then, you know, it really provides you with the documentation of your progress along this quality improvement journey. And so you're making decisions based on concrete data versus assumptions.

Josh Casey: Great, so yeah, so you can really see the areas where improvement's needed and then and measure progress against that. So, earlier you mentioned CLIA proficiency testing. Can you talk a little bit more about how metrics can help labs prepare for regulatory compliance?

Johanna Miller: Yeah, so, so the calculating Sigma metrics do not directly demonstrate compliance, right? They're no, there are no replacement for proficiency testing. However, they're invaluable because they can give you a preview of where you may or may not have issues with your proficiency testing. So then you can anticipate and correct any issues before the proficiency testing occurs. And again, the rule of thumb for that would be that you would want Sigma metrics of 3 or better.

Josh Casey: And 3 is really that's the midpoint in the scale, right?

Johanna Miller: Yeah, yeah, exactly. So, you know, as you, of course, as you get better, right, it's, as you get higher number that indicates a tighter performance. But really, I mean, as long as you're hitting that 3, it's, I mean, you're a 3 translates to a process where over 99% of the results fall inside those limits.

Josh Casey: So it's a very, it's a very high standard.

Johanna Miller: Yeah, Six Sigma is incredibly – can be a very, very high standard.

Josh Casey: OK, well, shifting from regulatory work to teamwork; what are some of the ways that metrics improve collaboration and communication within the lab?

Johanna Miller: Yeah, so I mean, some of the labs I've worked with have cited Sigma metrics as just a way to make it easier to get their staff on board for these quality improvements, right? So, when you have those engaging conversations and when you say to your staff, I would like you to do something differently. And you show them the data, then then that builds that trust because you're not just saying this because it's some idea that randomly popped into your head, right? There's a metric, and, you know, we know that all laboratorians, no matter what their role is, they care about the patient results that they put out, and they want to hold themselves to the highest standard, and if you have the data that says hey, you know, this particular analyte needs some improvement, that's, that will get their attention, and that's what I've heard from, from laboratorians that I've worked with, right, that it helps get their staff engaged. And Sigma metrics can also serve as a way to kind of have conversations with like physicians or other stakeholders, right? Because especially if you achieve Six Sigma, right, people kind of conceptually know what that means. They conceptually know that that's a very good thing, and it just adds to the confidence in those test results.



Josh Casey: Great, so it's really it's about creating consistency, accountability and quality across the team and across different departments within, say, a hospital where you've got the laboratorians and the clinicians and they're collaborating on the outcomes.

Johanna Miller: Yes, exactly.

Josh Casey: So for a lab that's just kind of getting started in this space, what would you tell them to expect when focusing on metric-driven projects like Six Sigma? What is, what does that process look like?

Johanna Miller: Sure. So, I would say it's important to expect that something like this is going to have multiple phases, right? So calculating your Sigma metrics or any metrics, right, that's really the first step. So you can calculate them manually, the Sigma metrics manually. Even better would be some sort of informatics solution or some sort of system in place to calculate for you automatically, but essentially you need to get to the point where the data is at your fingertips, and that's really the first phase. Then the next phase is all about reviewing that data. Is there any opportunity for improvement, ranking your assays to understand where to start, right? So you, so what you would do is you would start with the most significant issue first, and then the question becomes, is do you need more data to understand what next moves to take. You know, a lot of times I've seen laboratorians, they already often have ideas based on their personal experience or their knowledge. So I'll give an example, one of the things we often see would be that carbon dioxide has poor Sigma metrics and the most likely reason for that is usually common knowledge. I haven't met any laboratory that that is surprised by this, because that analyte is so volatile but it's really prone to evaporation and, you know, sometimes in the graph, it's so you can see the evaporation, but you can see, you know, the value changing and then it drifts a little each day and then it resets when a new vial that it drifts, then it resets, and it will look like a sawtooth pattern when you plot it. So in that case, you wouldn't necessarily do an additional investigation, you would just start to leverage your knowledge and skip straight to implementing changes. So for the carbon dioxide example, that would mean any opportunity to limit evaporation, and you know, for some of these analytes, these really volatile analytes, a little bit of an uphill battle, but any sort of modest improvement that you can get from putting your attention in that place it can make it so that your QC is more representative of the state of your analyzer. So that's another phase. So then after you approve one analyte, right, the next phase would be to just go down the list to the next one, right? And then the next one after that. So after this initial kickoff, you might have multiple improvements to make before you get to the point where you're just monitoring. And that's really the final phase, right, where you've gotten your Sigma metrics to the point where you're kind of content with them, and then all you do is you just pull new data in as it comes out and you just monitor. And getting to that point is really a beautiful thing because that really translates to confidence. So if there's ever a question from someone outside the lab on the quality of your results, you have the data to respond appropriately and provide those assurances. Because you know, hey, look, this is a 5 Sigma assay, and that's the trust that you can have in your results and that confidence that you can bring to those conversations.

Josh Casey: Is there, so it's interesting, is there is there an obvious place to start with the lab or is it really depend on the kind of majority of tests that they run that might be typical in a, you know, a reference laboratory versus hospital environment. You mentioned the carbon dioxide, which is the only reason why I asked, I imagine that there's some specific examples where you kind of look at one assay over another and say let's start with that.



Johanna Miller: So it depends, so in an ideal world, you would, you would have your sigma metrics for all your assays and then you'd kind of rank them. And then you're looking at the big picture. Now, if, for example, you didn't want to or it was just too tedious to calculate Sigma metrics across the board, what I found is that many laboratories kind of have a have a pretty good gut feel for which assays may need a little more attention. So in that case, maybe you would just calculate Sigma metrics for those couple analytes. They need attention, you could monitor those more closely.

Josh Casey: Got it. Makes sense. Related to the process, we know that a key member of the lab team is the diagnostic providers that they work with. What are some of the ways that labs can best collaborate with their partners when it comes to optimizing metrics?

Johanna Miller: Yeah, so, I mean when I hear the word collaborate, I automatically think communicate, right? So in this context, that's exactly right. That's exactly what I would say, right? So I think it's important that labs realize that their diagnostic partner is there for them and that they can call them for support, and it doesn't always have to be in the form of like a complaint, right? You can call for an inquiry, you can call to request more information. All of that is very common and very reasonable. Another phone call or another type of communication would be sort of your dedicated support person. So here at QuidelOrtho we call them field application specialist. These are the individuals they provide in-person technical support and in-person training to laboratories, and they're often, you know, kind of on the frontline of you know, in the trenches with you in the lab. And so they have a lot of knowledge, specifically about, you know, the products that they represent. And so, you know, you can ask them to observe your staff, you know, ask them to offer suggestions for workflow, you know, tell them which analytes you're focusing on, maybe they have some experience in that. At QuidelOrtho, those field application specialists, they're true experts and they're very, very passionate about helping customers. So I know that they would be happy to support in that way and then another way to collaborate would be around, you know, what kind of informatics tools are available. That's more along the lines of how can we help you make your job easier, right? How can we put insights at your fingertips, we spend less for doing calculations because everything's automated, but yeah, that's really what I would say, you know, leaning on technical support, whether it's on the phone or in person. And then seeing what tools are available.

Josh Casey: So it sounds like communication is key and, of course, it always pays to find the right partner. Thank you, Johanna.

Johanna Miller: Thank you for the wonderful discussion.

Josh Casey: So that's all the time we have for today. Thank you for sharing your insights on the value of metrics in the clinical laboratory. I hope everyone enjoyed the conversation. Please be sure to review the sections and links within the podcast description to learn more, and based on today's episode, I'll leave you with our pop quiz so you can test what you've learned. The question is, what quality metric can be used to understand whether your lab is at risk of potential proficiency testing issues? You can go back and listen again if you'd like more details. Thank you for joining us. Please subscribe to QuidelOrtho Science Bytes, our monthly podcast brought to you by QuidelOrtho Corporation, where we are transforming the power of diagnostics into a healthier future for all. Until next time, take care everyone.