Quality controls

A warning on warning rules

Are we warning ourselves to distraction?

What are soft warnings?

Does your smoke detector have a warning rule? If it did, would it have two alarms: one that says, “Hmm, there might be a fire” and another that indicates “HEY, THERE’S A FIRE!!!”? Probably not.

If your vehicle has collision alerts, does the alert come in two levels? “Hey, just wanted to say, you might be about to crash into another vehicle.” And “LOOK OUT! YOU’RE GOING TO CRASH!!!” Probably not. Most critical alerts we use in daily life don’t offer “soft warnings.” They only notify us about significant problems.

In contrast, many laboratories use warning rules for their quality control. They establish a control rule designed to trigger a semi-alarm. The way laboratories respond to the semi-alarm is often unique.

In the beginning, there was only 2SD

From a Westgard Rules perspective, the history of the 2 standard deviation (2SD) “warning rule” is a story of nudging; or, if you prefer a more ominous term, a story of social engineering. Before there were any multirule quality control (QC) procedures, laboratories essentially only used 2SD control limits. You ran controls, or possibly pooled patient samples, and plotted them on a Levey-Jennings Shewhart chart. Anything plotted beyond 2SD control limits was out-of-control, the run was rejected, and troubleshooting ensued.

Sten Westgard, MS
Director of Client Services and Technology, Westgard QC, Inc.

The downside of these rules is that 2SD limits are notoriously prone to false rejection. With two controls, the false rejection is around 9%, while with three controls that false rejection increases to around 14%. As the test menu of the early laboratories grew, false rejections proliferated. The chronic alarms generated another troublesome set of behaviors: repeating controls, running new controls, repeating those new controls, knee-jerk recalibrating, and worse. These activities resulted in time and money spent, all due to false alarms. It was clear 2SD limits could not continue to be used if the test menu and testing volume continued their ascent.

Enter Westgard Rules

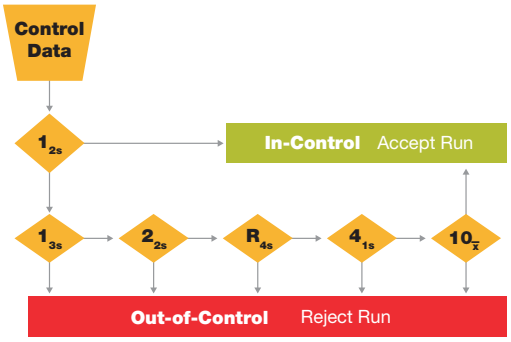
The multirule QC procedure, published in 1981, represented a breakthrough on many fronts. It was the first time a combination of QC procedures had been assessed for error detection and false rejection characteristics, making it possible to prove that the "Westgard Rules" could achieve high error detection without high false rejection. Instead of 9 to 14% false rejection, the rejection rates were 2 to 4%—a major gain. The replacement for 2SD control limits had been found.

But the tradition of 2SD limits and the habit of reacting to anything past 2SD remained deeply ingrained in laboratory staff. Furthermore, the interpretation of five rejection rules on every control data point was something laboratory professionals did not wish to contemplate. Remember, back in the early 1980s, there were no desktop computers. QC was a manual activity carried out by humans, not software algorithms. There was a need to slowly wean the staff away from 2SD rejections while also protecting their cognitive workload.

Consequently, the 2SD rule was transformed from a rejection into a warning. Lab staff responded to 2SD outliers, but only to check other rules (the five rejection rules from the Westgard Rules). Nothing was rejected by a 2SD outlier alone; there had to be another rule failure. This meant staff didn't have to interpret all the rules on every control point—they only had to do more work when a point exceeded the 2SD mark. Less work, less stress. Essentially the classic warning rule meant, "Something might have happened; take a closer look at the data."

That "nudge" of 2SD from rejection to warning, the dramatic reduction of false alarms, and the carefully balanced workload of rule interpretation combined to make the Westgard Rules a smashing success. It also helped that they were free—not patented, not commercially exclusive, but openly accessible to anyone. The Westgard Rules achieved global adoption in record time. It's hard to find a QC program or an instrument that doesn't include them.

The challenge of 2SD outliers endures. As lab menus exploded and testing volume scaled by orders of magnitude, even the "warnings" of 2SD began to chafe. Constant warnings meant no warnings at all. Labs suffered from "alarm fatigue" and stopped listening to the alerts. Responses were wasteful, such as repeating controls automatically—often multiple times—until they reached one "in" control so they could ignore all the previous "out" controls.



As laboratory informatics grow, do we still need a warning rule?

Today's laboratories—at least modern laboratories—don't have their lab staff draw control charts on paper, plot control points by hand, and individually interpret every point. It's done by informatics, perhaps on the instrument itself, or on an LIS, middleware, or a connected or separate software program.

Do we need to worry about the cognitive workload of a software algorithm? Heck, no. We can make the program interpret as many control rules as we want for every control point. There's plenty of processing capability these days. We don't need to give a warning or a heads-up to the informatics. The informatics can handle the load.

In that case, the classic Warning Rule is obsolete, and we can just test all the control points against rejection rules. We don't have to endure false warnings. But 2SD warnings are an addictive habit for some, and part of a tradition that has been handed down from generation to generation of laboratory professionals. They've always used 2SD and they tell every new lab tech on their first day, "This is how we've always done QC." And so the 2SD warning rule persists.

Undeniably, there is psychological comfort in responding to a warning that, most of the time, turns out to be a false alarm. We see an alert but we get the reassuring news that nothing's actually wrong. We've therefore proven that we're vigilant. We've demonstrated that we're doing our job. And we didn't have to make any real troubleshooting effort.

But at its core, the classic Warning Rule is now a waste of time. When it triggers and nothing has happened—when none of the rejection rules have been violated—we have done something for nothing. If we just let the computer check the appropriate rejection rules immediately, we can avoid some false alarms and focus only on the real problems, not the illusions.

A different kind of alert: Prospective Warning Rules

The popularity of classic Warning Rules has endured long past their utility, and in some cases, has mutated into a kind of added-waste policy. Rather than focus on warning rules that alert the laboratory to a possible existing problem, some laboratories now impose a rule that doesn't indicate a current problem but might predict an issue that will grow into a problem in the future.

This version, what we call a prospective warning rule, doesn't match up with any Westgard Rules flowchart, but it does give laboratories the ability to get ahead of issues. That is, before a problem grows so large that it actually causes a rejection of the run, the laboratory tries to catch the error when it's small. If you catch the error before it becomes critical, you may be able to fix it before any runs or any patient specimens are impacted.

Often the prospective warning rule is an 8:x or 10:x rule (for two levels of control), or 6:x, 9:x, or 12:x (for three levels of control). The number of values on one side of the mean could represent the beginning of a drift or shift, which might be inconsequential now (probably less than 1SD), but could grow into a significant problem later. It might be a warning to check the calibration or the age of the reagent lot, for example.

One problem with these prospective warning rules is the result of the massive growth of our laboratory systems. For labs that have more than one instrument or systems that have more than one laboratory, there is a temptation, often indulged, to "standardize" the QC on all instruments. That is, every instrument gets the same mean, whether or not that's the actual mean that exists. As a result, instruments that use the wrong (externally imposed) mean will inevitably see their control results skew off-center, an issue that will often manifest as 10:x rule violations. The "standardization" has caused more false alarms.

The use of prospective warning rules needs to be handled carefully. If your lab or labs are all "standardizing" their means, you cannot use a sensitive warning rule. Imposing a useful warning rule requires that you center the QC on the actual mean of the instrument and use the actual SD of the method (again, no "standardizing" of the SD or the QC gets skewed).

Going further still, laboratories can maximize their error detection and minimize their false rejections, as well as warnings, by calculating an analytical Sigma-metric and using a design tool like the Westgard Sigma Rules to streamline their QC. Using all the Westgard Rules on all tests, once the mantra of labs back in the 1980s and 1990s, is now highly discouraged. A more customized, optimized set of rules matching the QC to the performance of the methods in the context of the needs of the patient is recommended so you don't have to use all the Westgard Rules on many tests. Once you've pared away all the unnecessary rejection rules, you'll have a better idea of what prospective warning rules are available for use.

What about risk management?

There is a flip side to the elimination of both rejection and warning rules, though. When you reduce warnings and reduce rules, once you find an error it's significant, something you truly need to troubleshoot (you can't engage in the previous habits of repeating and recalibrating until you're back "in"). When you see an out-of-control flag from a lean QC system, that is a real fire; those patient values are impacted, you need to stop the results from going out the door.

With many laboratories, that out-of-control run now represents hundreds, thousands, or even tens of thousands of results. It may not even be possible to repeat that number of patient samples anymore. With lean testing capacity, one error is so big, there is no easy recovery.

For many lab professionals, excessive false alarms come with the security of catching a real error every once in a while, ideally when the error is smaller and impacts fewer patients. Of course, if we pursued this logic to its illogical end, we would run a control with every patient sample (indeed, some systems have effectively moved to this approach), so that every outlier only impacts the barest minimum of patients. The cost in QC, however, proves ruinous. We can't afford to run QC so frequently that we're no longer worried about patient impact. We have to find a middle ground.

That sweet spot of running enough controls, with the right mixture of control rules, is often dictated by regulations—which provide the floor—and financial constraints—which provide the ceiling—on what QC procedures can practically be implemented.

Summary

Choosing the right set of rejection rules and whether or not to add a prospective warning rule requires not only calculations but also the deeply learned skills of the laboratory professional. For cardiac markers, there is a different need for rejection and warning rules in comparison to some routine biochemistry tests. For this reason there is no simple answer for all tests, all instruments, and all labs. You have to adapt the Westgard Sigma Rules approach to your performance and your assessment of risk to the patients. Only you can manage this complex task.

Don't say you weren't warned.

Clinical Diagnostics

USA
46500 Kato Road
Fremont, CA 94538 USA
Tel. 800-232-3342 / +1 510-979-5000
sales.diagnostics.fmt@thermofisher.com

Asia Pacific
Tel: +65 6499 9999
cdd.asia.info2@thermofisher.com

Australia
Tel. +61 1800 333 110
auinfo@thermofisher.com

Canada
Tel. 905-286-4290
CDD.Canada@thermofisher.com

China
Tel. +86 400 650 5118
sales.china@thermofisher.com

France, Belgium (Brussels / Wallonia) & Luxembourg
Tel. +33 (0) 1 40 86 65 00
cdx.fr.info@thermofisher.com

Germany
Tel. +49 (0) 3302 883 608
cdx.de.info@thermofisher.com

Hong Kong
Tel. +852 3107 7600
SDG.HK.Sales@thermofisher.com

Italy
distributor.cdd@thermofisher.com

Japan
Tel. +81 (0) 120 489 211
JPYOK-CDD.QC@thermofisher.com

Netherlands & Belgium (Flemish)
Tel. +49 3302 883 660
Info.benelux.cdd@thermofisher.com

New Zealand
Tel. +61 0800933 966
nzinfo@thermofisher.co.nz

Nordic
Tel. +46 8 594 691 30
info.nordic.cdd@thermofisher.com

Russia
Tel. +7 495 739 76 41
info.btd.moscow@thermofisher.com

South Africa
Tel. +27 11 792 6790
support-za.idd@thermofisher.com

Spain & Portugal (Iberia)
Tel. +34 93589 8338
CDD.Info.ES@thermofisher.com

Switzerland & Austria
Tel. +41 26 663 86 70
cdx.ch.info@thermofisher.com

United Kingdom & Ireland
Tel. +44 1442 868 940
cdx.UK.info@thermofisher.com

For Countries Not Listed
distributor.cdd@thermofisher.com

Learn more at **thermofisher.com/masqc**

thermo scientific