

Are There Westgard Rules in Your Future? The Current Devolution and Future Revolution in QC Practices

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In 1981, a short paper appeared in the journal of Clinical Chemistry entitled, "A multi-rule Shewhart chart for quality control in clinical chemistry" – and sparked an upheaval in QC for laboratories around the world. What was meant to provide a simple example of how to combine multiple control rules and numbers of control measurements rapidly became what is now popularly known as the "Westgard Rules"; a single QC procedure currently implemented by nearly 75% of laboratories worldwide. For a time, "Westgard Rules" was synonymous with best practices for QC, and it appeared to be a tool that could be applied everywhere for all tests and all laboratories.

In 2019, 38 years later, the popularity of "Westgard Rules" is not quite as stellar, and its practical usefulness is increasingly questioned. Given the latest generation of engineering, better precision methods, more automated instruments, are "Westgard Rules" still necessary? Given the sheer volume of testing, can an lab afford to troubleshoot all the outliers generated by the complete set of "Westgard Rules"? Since these rules were created before the era of fully automated instruments, before the existence of computer software for QC charting, before LIS systems, before middleware, before informatics, big data, and even before ISO 15189 and measurement uncertainty, is it possible that "Westgard Rules" have outlived their usefulness?

The answer to this question is not simply "yes" or "no". Even the most recent instruments are not uniformly world class in quality. If anything, the proliferation of new instruments and small devices, new methods, and new tests has meant that there is a greater need for robust QC procedures, which may include multirule approaches. Happily, however, there are indeed methods that achieve the highest levels of analytical quality – Six Sigma – where the number of rules and controls can be pared down to an appropriate minimum.

Unbeknownst to many, just as instruments and laboratory testing have evolved, so, too, have "Westgard Rules" changed with the times. In the last two decades, updated versions of "Westgard Rules" have been released. Just as the original set of "Westgard Rules" were neither patented nor commercially exclusive, so too are these new versions available free to the public. "Westgard Sigma Rules" is a new form of multirules that adjusts the number of rules and control measurements to take into account the analytical Sigma-metric of the test method. In 2018, an even more advanced version of "Westgard Sigma Rules" was released that incorporates Parvin's MaxE(Nuf) model, so that the Sigma-metric can now be leveraged to determine the frequency of running controls, in addition to the number of controls and rules that need to be implemented.

The result of all these developments is that laboratories have a practical, flexible tool available to them that can answer every question about the use of QC on their methods. How many rules? How many controls? How often should controls be run? All that can be answered in a data-driven, evidence-based approach with "Westgard Rules" and Six Sigma.