

**DIAGNOSTICS**

# SIX SIGMA: Laboratory Quality Control in the Healthcare Ecosystem

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## WHY QUALITY MATTERS IN THE HEALTHCARE ECOSYSTEM

Quality control testing is a vital point of any clinical laboratory's workflow, ensuring that assays and protocols are working as expected, and that the results reported to hospital clinicians and doctors are correct. Effective quality control (QC) is a careful balance – too little QC testing

could lead to erroneous results, while excessive testing places unnecessary strain on resources. Understanding the QC requirements of your assays, protocols and workflows is therefore vital to providing a fast, efficient service, as well as releasing trapped cash within your laboratory budget.

## THE BENEFITS OF EFFICIENCY – MOVING QC INTO THE 21ST CENTURY

QC testing is fundamentally a balance between safety and efficiency, and so it is desirable to carry out the minimal amount of testing necessary to maintain assay performance. The 'Westgard rules' have been used by laboratories around the world for many years, applying multiple control rules to judge the acceptability of an analytical test or run. This system allows laboratories to detect both random and systematic errors by defining specific performance limits for a particular assay. However, for highly reproducible,

automated laboratory testing, application of full Westgard Rules may not be necessary. If an assay is of sufficiently high quality, and suitably rigorous maintenance schedules are in place, then the risk of erroneous results is significantly reduced. In these cases, we can redesign QC testing strategies to reflect the reliability of the assay, freeing up staff time and other resources. To achieve these efficiency savings, we need new tools for the assessment, assurance and optimization of laboratory processes.



## WHAT IS SIX SIGMA?

Sigma metrics are an internationally recognized system of process improvement that has been used in the healthcare sector for more than 15 years. But what are they? At the heart of sigma metrics is a simple question: how many defects/errors occur per million opportunities? For each process (assay), a Total Error Allowable (TEa) is established according to predefined industry standards (MAPS, CLIA or similar for clinical laboratories). The Sigma-metric equation measures how performance of the assay compares to this TEa, based on the observed standard deviation and bias:

$$\text{Sigma} = \frac{\text{TEa} - \text{bias}}{\text{CV}}$$

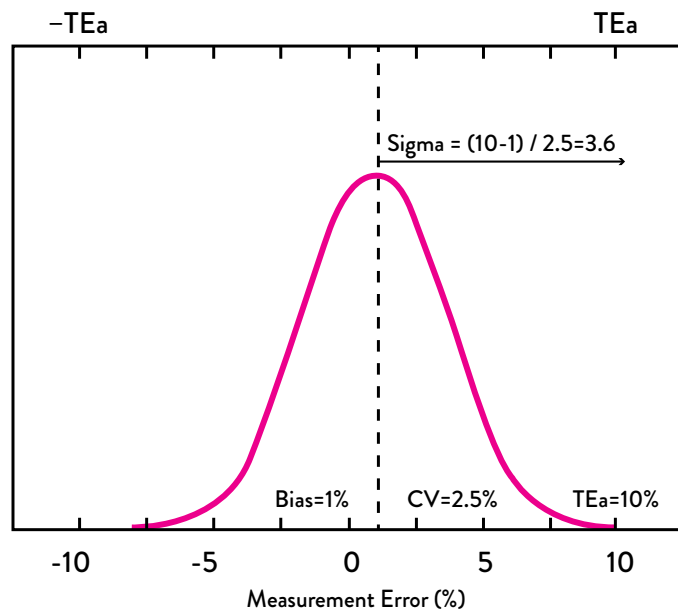


Figure 1: Sigma metrics provide a quantitative measurement of performance compared to a predefined standard.

The ideal situation is obviously for no errors to occur at all, but in reality this is not possible. A short-term Sigma value of six (3.6 defects per million, DPM) is therefore considered an optimal process (a short-term Sigma value of three or approximately 67,000 DPM is considered the minimum acceptable standard outside of the healthcare industry).

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## FIT FOR PURPOSE?

Sigma metrics allow laboratories to compare their assays and processes with those used in other laboratories (even those using different assay kits or protocols), providing a useful marker of performance and identifying areas for improvement. More importantly, it offers a straightforward tool for identifying if a given analytical run is performing within the acceptable tolerances (TEa) of the assay. A Method Decision chart provides a clear visual representation of this decision-making process, categorizing analytical performance as ‘world class’, ‘excellent’, ‘good’, ‘marginal’, ‘poor’ or ‘unacceptable.’

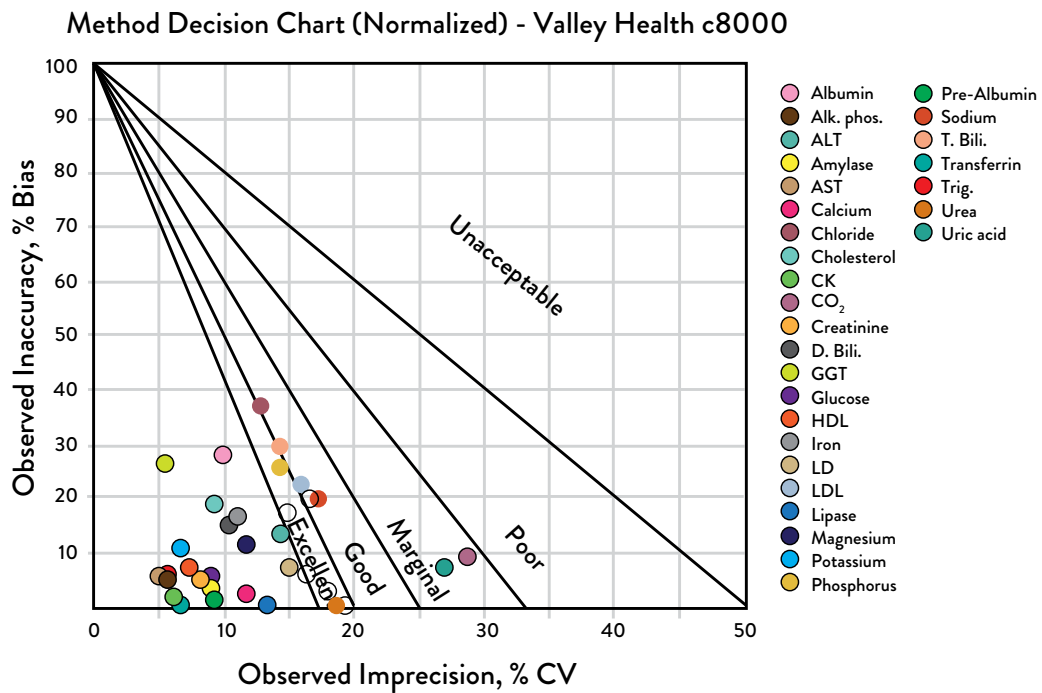


Figure 2: Normalized method decision chart showing the performance of 29 analytes on Abbott’s ARCHITECT c8000 immunochemistry system at Valley Health’s Winchester Medical Center (Virginia, USA).<sup>1</sup>

## REALIZING THE BENEFITS – RELEASING TRAPPED CASH

The ultimate goal of all QC activities is to improve patient care by providing clinicians with a more accurate biochemical picture. Although the clinical impact of erroneous laboratory results can vary significantly<sup>2</sup>, both in terms of patient outcomes and ongoing costs, the benefits of ‘right first time’ testing, and a more streamlined QC testing regime, are numerous – from freeing up instrument capacity and faster turnaround times to lower instrument downtime and improved staff morale.

All of these gains rely on the use of accurate and reliable assays, but are all commercially available assays really ‘high quality methods’? Figure 3 compares performance estimates of automated testing platforms calculated by the laboratory director at Valley Health’s Winchester Medical Center (Virginia, USA). The significant variation in performance between instruments and assays clearly shows the need to understand the exact performance criteria of each assay, ensuring unreliable or incorrect results are not released from the laboratory. Overall, these results demonstrate the importance of working with a trusted diagnostic partner capable of delivering high quality solutions and services to meet laboratory needs.

	<b>&gt;6.0</b> (WORLD CLASS)	<b>5.0</b> (EXCELLENT)	<b>4.0</b> (GOOD)	<b>3.0</b> (MARGINAL)	<b>&lt;3.0</b> (UNACCEPTABLE)
<b>ABBOTT</b>	53%	20%	13%	13%	0%
<b>VENDOR 2</b>	45%	14%	17%	10%	14%
<b>VENDOR 3</b>	23%	30%	17%	27%	3%
<b>VENDOR 4</b>	30%	13%	13%	30%	13%
<b>VENDOR 5</b>	50%	0%	17%	20%	13%
<b>VENDOR 6</b>	30%	13%	20%	20%	17%

Figure 3: Estimated performance comparison of 30 clinical chemistry tests using automated instruments from six manufacturers performed by Valley Health’s Winchester Medical Center.<sup>1</sup>

## CONCLUSIONS

Like all aspects of clinical laboratory practice, QC testing needs to evolve to meet the challenges of the modern healthcare ecosystem. Streamlining QC activities to reduce their cost and impact on productivity requires laboratories to employ high quality, reliable assays and solutions which can achieve ‘right first time’ performance. Investment in these technologies will lead to fewer errors and a decrease in repeat testing, limiting the burden of QC and, ultimately, improving laboratory efficiency for reduced overall costs.

The ultimate goal of all QC activities is to improve patient care by providing clinicians with a more accurate biochemical picture.

## References

1. Westgard, J, Litten, J & Adeli, K (2012). Clinical chemistry current events: Sigma metrics driven quality management in the clinical laboratory and advances in pediatric reference intervals. AACC 2012 Industry Workshop
2. Tse Ping Loh et al. (2013). Journal of Clinical Pathology, 66 (3), 260-261

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