Application of Westgard Sigma Multi-Rules as quality assessment tool in clinical research laboratory

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ABSTRACT

Introduction: Multi rule Quality control (QC) has been implemented in laboratories to ensure the reliability of test results in clinical decision-making process. However, a proliferation of all of these rules can result in a lack of coherence in quality. In order to achieve top-notch quality in a clinical research laboratory, it is essential to establish optimal Westgard QC Rules. **Methods:** A retrospective study was conducted on a data set consisting of internal quality control and external quality control of 30 assays collected between January 2021 and June 2022. The sigma metrics (σCLIA, σBV) of these assays run on automated haematology analyser (Sysmex XS1000i) and automated dry chemistry analyser (Fuji Dri-Chem NX500) was calculated based on imprecision (CV%), inaccuracy (bias %), total allowable error (TEa) with the formula of Sigma = (TEa-bias)/CV. **Results:** Nine out of 30 assays achieved Six Sigma quality performance, which showed $\sigma \geq 6$. Thirteen assays described $\sigma>3$, which met the process performance in a clinical research laboratory setting while the remaining eight assays failed to achieve the minimum six sigma quality performance with metrics less than three. **Conclusion:** Westgard sigma rules are essential for timely error detection and scrutinize between the two most common sources of error; bias and imprecision. This serves as a gold standard for obtaining high quality test.