Selection of the Primary Quality Control Rules Based on Total Allowable Error and Total Error (by Hand or Laptop)

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ABSTRACT

Choosing quality control (QC) rules for monitoring quantitative methods is compulsory, often frustrating, and not easy. As part of the protocol, there are many possible QC statistical "rules" (eg, rejecting a single value outside 2 SDs) to be selected. Each analyte should use the rule or rules that have the fewest accepted wrong results (for patients and controls). Selecting the best primary QC rule ensures the development of a simple, rapid system that calculates the rule best primary for each level used for an analyte. The algorithm uses 3 readily available data points for each QC level—the laboratory's mean, SD, and the true (survey) mean. With these data and the total error allowable (TEa), the program calculates the values for the total error (TE) and Tea − TE. This algorithm generates the primary QC rule (eg, 12 SD, 2.5 SD, 13 SD rule). The rules, −12.5 or 13 SDs (and ones in between if wanted), will reduce wrong results without accepting false results. Additionally, QC rules such as 41 SD and 10 SD are no longer necessary. The 22-SD rule need not be rejected, but the user need only be aware. Using the algorithm by hand or laptop is easy and removes the guesswork of choosing the primary QC rules.

ABBREVIATIONS: QC - quality control, Tea - total error allowable, TE - total error.

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