

Validating the Performance of QC Procedures

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KEYWORDS

- Quality control • Out-of-control condition • QC performance evaluation
- Statistical QC

KEY POINTS

- The performance of quality control procedures can be validated by assessing the expected number of unreliable patient results produced because of an out-of-control condition for a given quality control strategy and determining if the risk of producing and reporting unreliable patient results is acceptable.
- The expected number of unreliable patient results reported before and after the last accepted quality control evaluation before the detection of an out-of-control condition can be used as design criteria for quality control strategies that meet a laboratory's risk criteria.
- A methodology for computing the expected number of unreliable patient results produced because of an out-of-control condition for a given quality control strategy is presented.

INTRODUCTION TO QC PERFORMANCE VALIDATION

With the introduction of risk management for development of laboratory quality control (QC) plans, many different types of controls may be used to monitor the performance of an analytical process and hopefully detect any errors that may occur. Some of these controls are provided by the manufacturer and built into the analyzer. Others, such as statistical QC procedures, are implemented by the laboratory to provide an independent monitor of performance. Still others are implemented by the laboratory to monitor specific faults or causes of errors, such as specimen integrity and suitability for analysis. Given that the purpose of the QC plan is to detect problems that may occur, it is important to evaluate the detection capabilities of different controls and ensure they will indeed be able to detect medically important errors.

For some controls (eg, training of analysts), it is difficult to assess their effectiveness. For other controls, such as those implemented by the manufacturer (eg, short sample detector), the manufacturer should have experimental evidence to prove the

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