Sunway Medical Laboratory Quality Control Plans Based on Six Sigma, Risk Management and Uncertainty

Jamuna Jairaman, BSc, MPH*, Zarinah Sakiman, BSc, Lee Suan Li, BSc

KEYWORDS

• Analytical quality control • Six Sigma • Risk management • Uncertainty

KEY POINTS

- Measurement uncertainty, risk management, and Sigma metrics are often discussed as individual approaches, sometimes in conflict with each other. But in truth, these approaches can all be implemented together and provide complementary strength in assuring the quality of laboratory testing.
- Sustained effort and implementation of Sigma metrics result in continuous improvement of assay quality and reductions in costs and defective test results.
- Sigma metrics provide not only assistance in optimizing routine laboratory operation but also greatly assist in the selection of appropriate new instruments and methodology.
- Risk management allows laboratories to expand their quality assurance to cover the total testing process.
- Measurement uncertainty is an essential calculation for International Organization for Standardization 15189 certification, but often these figures are not routinely reported with patient test results and requires the greatest effort to educate laboratorians and clinicians about the meaningful use of these estimates.

INTRODUCTION

Any laboratory total testing process involves 3 major phases: the preanalytical, analytical, and postanalytical phases. All 3 areas can contribute to sources of errors resulting in poor patient care. Studies in the 1990s and 2000s led many to believe that about 80% of the errors are found in the preanalytical and postanalytical phases, whereas

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Pathology Laboratory Department, Sunway Medical Centre Sdn Bhd, No. 5 Jalan Lagoon Selatan, Bandar Sunway, Selangor 47500, Malaysia
* Corresponding author.
E-mail address: jamunaj@sunway.com.my

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