Analytical Performance of Creatinine Methods: A Proficiency Testing Provider Perspective

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INTRODUCTION

The US National Institutes of Health established The National Kidney Disease Education Program (NKDEP) in 2000 to address the kidney disease epidemic. NKDEP’s Laboratory Working Group (LWG) was tasked to resolve the issues in the measurement of serum creatinine that was used in the estimation of Glomerular Filtration Rate (GFR). Bias and imprecision in the creatinine measurement has a large impact on the estimated GFR and the early detection of kidney disease.

The Laboratory Working Group developed and published recommendations to improve the standardization of creatinine measurements in 2006.1 Following this, Standard Reference Material SRM 967 was introduced in early 2007 and later superseded by SRM 967a in 2009. Existence of accuracy-based proficiency testing (PT) programs that use commutable serum materials and target values traceable to IDMS reference measurement procedures have been invaluable in monitoring standardized efforts. The Institute for Quality Management in Healthcare (IQMH) provides ISO 17043:2010 accredited PT programs for creatinine. Data was analyzed for method bias and imprecision to evaluate changes in performance over the last ten years.

METHODS

IQMH provides PT programs for medical laboratories in Canada and internationally. This study consists of the retrospective review of the accuracy-based PT program for serum creatinine. Seventy-nine survey materials that were distributed between May 2005 and May 2015 were analyzed to observe changes in the creatinine measurement methods in routine use. Native and spiked human sera were used as PT specimens. Reference results were obtained using an IDMS-traceable measurement procedure. To determine the method bias for each survey material, participant results were assessed against the reference results with pre-determined criteria. Robust statistics recommended in ISO 13528:2005 Statistical methods for use in proficiency testing by interlaboratory comparisons were used to calculate peer group means and standard deviations to eliminate the effects of outliers. Although only some methods were initially traceable to IDMS in 2005, eventually all participants used commercially available assays traceable to IDMS.

CONCLUSIONS

1. Creatinine method performance is very much dependent on the concentration. At concentrations below 11 mg/dL, method biases and CVs tended to be higher than at concentrations ≥11 mg/dL.
2. Over the study period, method biases tended to decline. However, there was no significant change in peer group CVs, although a small increment was observed.
3. In spite of the international standardization efforts, creatinine CV and bias continue to vary considerably among manufacturers.

REFERENCES