Verification of Quantitative Measurement of Urinary Creatinine Enzymatic Method Kit by DIRUI CS-T240 Clinical Chemistry Analyser

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ABSTRACT

Introduction: All urine samples sent for the diagnosis of inborn errors of metabolism (IEM) disorders testing will be first analysed for their creatinine levels. The urine creatinine analysis is applied either for calculation of urine amount needed in other tests or for quantitation of analytes per mol creatinine. Jaffe kinetic-end point method has been the preferred method. We aim to verify the performance of DIRUI enzymatic method reagent kit on DIRUI CS-T240 analyser and compare with Randox Jaffe kinetic-end point method reagent kit on same platform.

Method: Precision study, linearity and method comparisons were carried out using three levels of internal quality control (IQC) samples and the measured results were compared against manufacturer’s claims, medical decision limit and biological variation (BV).

Results: The within run coefficient variation (CV) were 3.57%, 2.61% and 1.35% for IQC Level 1, 2 and 3 respectively. The total precision and accuracy were 9.59% and 0.27% for Level 1, 3.17% and 0.57% for Level 2, while 2.03% and 3.63% for Level 3. Whereas, the verification value for CV based on analytical performance specifications (APS) BV desirable for CV and accuracy were 18.2% and 12.2% respectively. These values were compared, and the precision study was acceptable within desirable specification. Linearity met the manufacturer’s claim and range from 0.32 to 21.2mmol/L. The method comparison gave good correlation, $r^2$ of 0.9975 and regression equation, $y=0.9852x-0.022$ with medical decision limit, 0.53mmol/L. The assessment of acceptability of this new method was acceptable as calculated total error (TEc) < total allowable error (TEa) (APS BV Desirable for TEa = 42.1%).

Conclusion: The analytical verification study that we had carried out fulfilled the BV desirable in precision, accuracy and TEa. Therefore, the performances of enzymatic method kit on DIRUI CS-T240 analyser is verified to be fit-for-purpose and can replace the existing method.

Keywords: Creatinine, Method verification, DIRUI CS-T240, Enzymatic, Jaffe method.