Nephrology Dialysis Transplantation 31 (Supplement 1): i160–i172, 2016
doi:10.1093/ndt/gfw163.12

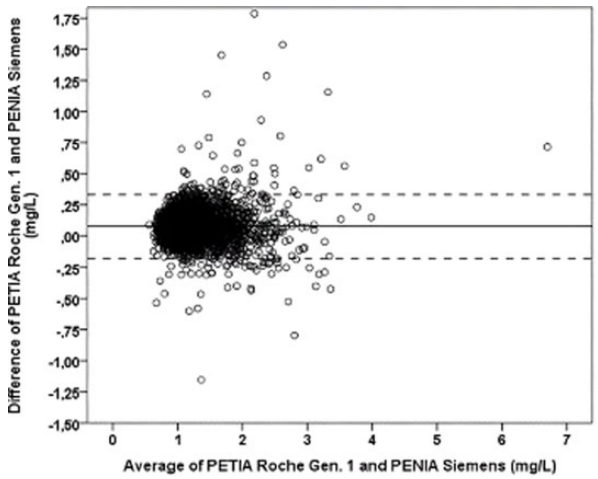
CHRONIC KIDNEY DISEASE. LAB METHODS, GFR MEASUREMENT, URINE PROTEOMICS

SP231 CYSTATIN C STANDARDIZATION DECREASES ASSAY VARIATION AND IMPROVES ASSESSMENT OF GFR

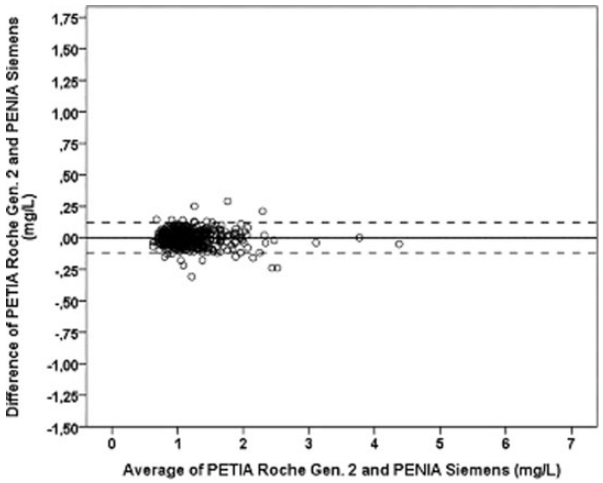
Natalie Ebert[1], Pierre Delanaye[2], Mike Shlipak[3], Olga Jakob[4], Peter Martus[5], Jens Gaedeke[6], Mirjam Schuchardt[6], Markus van der Giet[6], Jan Bartel[7], Etienne Cavallier[8] and Elke Schaeffner[9]

[1]Charité, Nephrology, Berlin, GERMANY, [2]University Sart-Tilman, Nephrology, Liège, BELGIUM, [3]UCSF, Gen Int Med, San Francisco, CA, [4]Charité, Biostat, Berlin, GERMANY, [5]EK- Univ, Biostat, Tübingen, GERMANY, [6]Charite, Nephrol, Berlin, GERMANY, [7]Labor Limbach, Clin Chem, Heidelberg, GERMANY, [8]Univ Sart-Tilman, Clin Chem, Liège, BELGIUM, [9]Charité, Pub Health, Berlin, GERMANY

Introduction and Aims: Cystatin C is increasingly used in equations for estimating GFR. The dependence of cysC results upon the analytical method has been a major source of controversy and uncertainty.
Methods: CysC was measured with non-standardized turbidimetric Roche Generation 1 and standardized nephelometric Siemens assays in 3666 blood samples of the Berlin Initiative Study. Additionally, cysC was measured with standardized Roche Generation 2 and Siemens in 567 samples. CysC-based eGFR was assessed with CKD-EPIcys (Chronic Kidney Disease Epidemiology) and CAPA (Caucasian, Asian, Pediatric, Adult) equations and the impact of the assays on eGFR was determined. Equation performance compared to mGFR was evaluated.
Results: Concordance of Roche Gen2 and Siemens was high with median difference of 0.003±0.13mg/L (limits of agreement: -0.12 to 0.12) and Passing Bablok correlation was essentially perfect Figure 1:*Bland and Altman of PETIA Roche Gen2 versus PENIA Siemens cystatin C (mg/L) assay (n=567). The bias is represented by the solid middle line (0.003 mg/L). The upper (0.12 mg/L) and lower limits (-0.12 mg/L) of the interval of agreement are represented by the dashed lines.*



Non-standardized Roche Gen1 assay showed worse concordance with Siemens: median difference was 0.08±0.13mg/L (limits of agreement: -0.18 to 0.34) and Passing Bablok correlation was inferior Figure 2: *Bland and Altman of PETIA Roche Gen1 versus PENIA Siemens cystatin C (mg/L) assay (n=3666). The bias is represented by the solid middle line (0.08 mg/L). The upper (0.38 mg/L) and lower limits (-0.18 mg/L) of the interval of agreement are represented by the dashed lines.*



Mean difference (±SD) of estimated $GFR_{CKD-EPI}$ was 0±4mL/min/1.73m² for Gen2 and Siemens as compared to -5±8 with Gen1. Performance of cystatin C-based GFR-equations was not influenced by the choice of Siemens or Gen2 assays.
Conclusions: Standardization of Roche Gen2 assay has led to improved accuracy of cysC measurement procedure compared to Siemens suggesting only negligible method bias and resulting in equal performance of both assays when estimating KF. This work indicates that successful calibration has led to major progress in cysC analysis.