

## Background and Objective

Cystatin C (CysC) serves as serum-based marker for assessing the estimated glomerular filtration rate (eGFR). Being independent from the muscle mass of the individual patient it has advantages over creatinine-based eGFR.

With the introduction of a novel CysC assay format for the Abbott Alinity c platform (CysC\_A), a method comparison study was undertaken with the Roche Cobas c platform implementation (CysC\_R).

## Methods

Over one month seventy samples from routine measurements with CysC\_R (TinaQuant, ID 06600239 190) were evaluated in parallel with CysC\_A (Sentinel, ID 06T32-30). According to the package inserts, both assays are traceable to ERM-DA471/IFCC.

CysC based eGFR was calculated using gender- and age-adjusted CKD-EPI formulas [1], and statistical evaluation was performed after anonymization with MedCalc 20.019. KDIGO classification G1–G5 followed the AGLA [2].

## Literature

- [1] Leseley A, Inker M.D., Christopher H, et al, Estimating Glomerular Filtration Rate from Serum Creatinine and Cystatin C. N Engl J Med 2012;367:20-29.  
[2] <https://agla.ch/de/rechner-und-tools/niereninsuffizienz>.

## Conclusions

Pasing and Bablok **regression analysis** showed highly correlated data: CysC\_A = 1.04\*CysC\_R–0.12 mg/l with Spearman’s rho = 0.98 [95% CI 0.97 to 0.99].

Bland-Altman **bias analysis** revealed a negative absolute method bias of –0.08 mg/l [95% CI –0.07 to –0.09 mg/l] corresponding to a relative –8.9% [95% CI –7.8 to –9.9%] method bias of CysC\_A relative to CysC\_R.

CysC\_A derived **average eGFR** was 8.8% [95% CI 7.8 to 9.8%] higher than CysC\_R eGFR with a 2S-scatter range of ±8.5%.

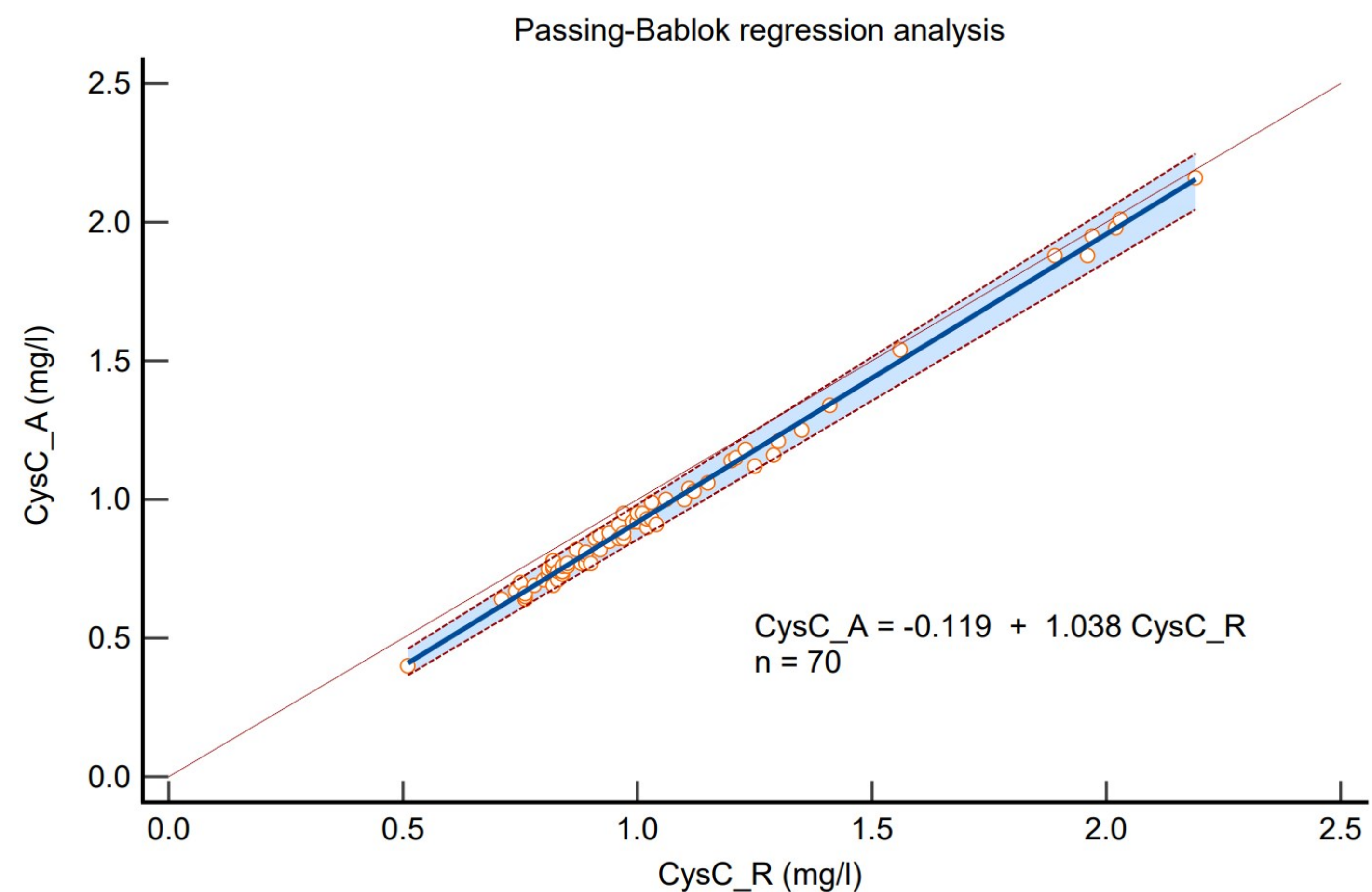
The CysC eGFR based **CKD KDIGO classification** showed class agreement with a Cohen's kappa of 0.86 [95% CI 0.77 to 0.95].

Classification **differences** were **limited to G1 and G2**, accounting for 79% of all cases. CysC\_A led to 40 G1 and 15 G2 classifications, while CysC\_R led to 29 G1 and 26 G2 classifications.

The comparison of these two IVD-CE-CysC assays revealed limited quantitative differences that are most likely not clinically significant.

Since this investigation was limited in terms of space and time, it cannot be concluded that the average deviation of the inter-assay results found in this study represents a statistically sound systematic error contribution.

## Results



Inter-rater agreement (kappa)

	KDIGO eGFR CysC_R						
	G1	G2	G3a	G3b	G4	Sum (%)	
KDIGO eGFR CysC_A	G1	29	11	0	0	0	40 (57)
	G2	0	15	0	0	0	15 (22)
	G3a	0	0	7	0	0	7 (10)
	G3b	0	0	0	5	0	5 (7)
	G4	0	0	0	0	3	3 (4)
Sum (%)	29 (42)	26 (37)	7 (10)	5 (7)	3 (4)	70	

Weighted Kappa 0.86 (95% CI 0.78 to 0.97)

