Concordance assessment of StatSensor Creatinine compared to a Central Laboratory enzymatic method for identifying chronic kidney disease stages 3-5 (eGFR <60 ml/min/1.73m)

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Background
Chronic kidney disease (CKD) is now recognised to be a major global public health problem The incidence of CKD in the Netherlands is reported to be between 6.7 – 10.4%. Individuals with CKD are at risk of exacerbating renal insufficiency if exposed to potentially nephrotoxic treatment such as drugs (ACE inhibitors, antibiotics, antifungals and anti-inflammatories) or radiological contrast medium. Identifying patients with CKD prior to exposure to a potentially nephrotoxic treatment will reduce the risk of exacerbating CKD. New Dutch Federation Nephrology guidelines indicate that administration of nephrotoxic medication should be avoided for anyone with a GFR < 45 ml/min/1.73 m2, and in people with a GFR 45-60 ml/min/1.73 m2 with either diabetes or 2 or more risk factors such as cardiovascular complications. A point of care (POC) creatinine methods would provide an opportunity for an assessment of kidney function as an aid to determine the risk associated with a potentially nephrotoxic treatment. StatSensor® Creatinine is a creatinine point of care device. The aim of this study is to assess the utility of StatSensor® whole blood creatinine monitoring system for identifying individuals/patients with chronic kidney disease stages 3-5 (eGFR <60 ml/min/1.73m).

Methods
Finger prick capillary blood from patients attending dialysis and general outpatient clinics was collected and tested on the StatSensor® Creatinine (Nova Biomedical). At the same time venous blood was collected and tested on Cobas Integra P800 analyzer (Roche Diagnostics) utilising a creatinine enzymatic method. The IDMS-traceable abbreviated Modification of Diet in Renal Disease (MDRD) equation was used to estimate and report estimated GFR. Concordance analysis was performed using eGFR criteria, <30, <45 and <60ml/min/1.73m.

Results
A total of 48 patients were tested including 26 dialysis patients and 22 general hospital outpatients, creatinine values ranged from 36.2 to 1140 µmol/L and MDRD eGFR values ranged from 3.6 to 211.7 ml/min/1.73m. The sensitivity and specificity for identifying patients with severe kidney function <30 ml/min/1.73m was 96.3 and 100% respectively. The sensitivity and specificity for identifying patients with moderate to severe kidney function <45 ml/min/1.73m was 93.4% and 100% respectively . The sensitivity and specificity for identifying patients with mild to moderate kidney function <60ml/min/1.73m was 88.2% and 92.9% respectively.

Method	Cobas 800				Cobas 800				Cobas 800			
StatSensor Creatinine	eGFR	<30	>30	No.	eGFR	<45	>45	No.	eGFR	<60	>60	No.
	<30	26	0	26	<45	29	0	29	<60	30	1	31
	>30	1	21	22	>45	2	17	29	>60	4	13	17
	No.	27	21	48	No.	31	17	48	No.	34	14	48
Sensitivity (%)	96.3				93.4				88.2			
False positive rate (%)	0.00				0.00				7.14			
Specificity (%)	100.0				100.0				92.9			
False negative rate (%)	3.7				6.45				11.8			
PPV	100.0				100.0				96.8			
NPV	95.5				89.5				76.5			
Concordance	97.9				95.8				89.6			

Conclusions
The data demonstrates that StatSensor® creatinine has a great potential for identifying patients with CKD stages 3-5 who may be at risk when administered nephrotoxic drugs. Further research is warranted to complete the data.