

## **Rapid bedside assessment of the renal function of patients undergoing contrast-enhanced CT. Is it a reliable approach for identifying patients at risk of a contrast medium adverse reaction ?.**

**Poster No.:** C-2669  
**Congress:** ECR 2013  
**Type:** Scientific Exhibit  
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**Keywords:** CT, Kidney, Contrast agents, Laboratory tests, Drugs / Reactions  
**DOI:** 10.1594/ecr2013/C-2669

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## Purpose

Impaired renal excretory function is the most significant risk factor for contrast induced nephropathy (CIN) and nephrogenic systemic fibrosis (NSF). Thus, measurement of serum creatinine and calculation of estimated glomerular filtration rate (eGFR) is mandatory before administration of iodinated or Gd-based contrast agents, especially in high-risk patients. As routine laboratory creatinine measurement is a time-consuming procedure especially in radiologic practice and in an out-patient setting, it would be desirable to have a fast and reliable tool for point-of-care (POC) creatinine measurement.

The StatSensor® Creatinine Hospital Meter (Nova Biomedical, Cheshire, UK) is a handheld analyzer for whole blood creatinine testing. It allows POC measurement of creatinine of arterial, venous or capillary blood and consecutive calculation of eGFR. The aim of this prospective clinical trial was to test its diagnostic reliability in a routine clinical setting of a radiologic department with in- and out-patient service.

## Methods and Materials

This was a prospective study of 612 patients who were scheduled for contrast enhanced computed tomography. Whole blood capillary and venous samples were collected and measured with StatSensor® Creatinine and compared to a venous blood sample measured by the central laboratory method (reference method) Estimated glomerular filtration rate (eGFR) was calculated by the Cockcroft-Gault equation. Bland-Altman plots were used for the evaluation of measurement agreement. An eGFR of 60, 45 and 30 ml/min/1.73m<sup>2</sup> was chosen to distinguish between normal and abnormal renal function, respectively.

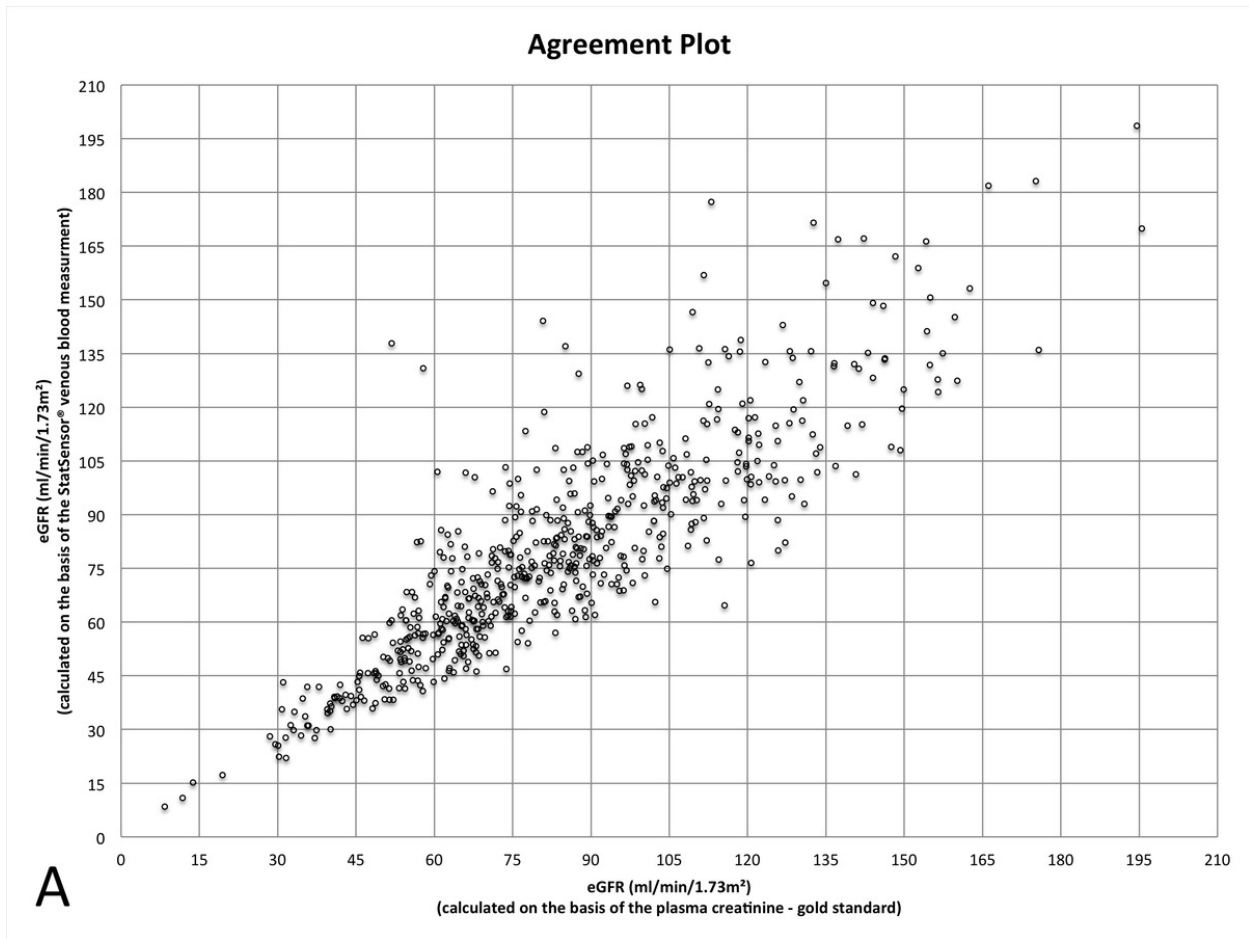
## Results

The laboratory gold standard yielded a significantly higher mean eGFR value when compared to the capillary and venous blood analysis of the StatSensor® ( $p < 0.001$ , respectively). Agreement plots and Bland-Altman plots for the venous measurements are shown in Figures 1 and 2, those for the capillary measurement are shown in Figure 3 and 4. These plots show a good agreement of eGFR-values calculated on the basis of the StatSensor® creatinine measurements and the gold standard. This was especially true for patients with an eGFR  $< 90$  ml/min/1.73m<sup>2</sup>. Diagnostic accuracy of the StatSensor® was evaluated by its potential to discriminate patients with normal from those with abnormal renal function, with an eGFR of 30, 45 and 60 ml/min/1.73m<sup>2</sup> as cut-off, respectively. Table 2 gives information about sensitivity, specificity, positive and negative predictive values and accuracy when compared to the gold-standard.

Sample	Cut-off eGFR (ml/min/1.73m <sup>2</sup> )	Sensitivity	Specificity	ppV	npV	Accuracy
Capillary Blood	60	0.87	0.87	0.62	0.96	0.87
	45	1.00	0.95	0.60	1.00	0.96
	30	1.00	0.99	0.40	1.00	0.99
Venous Blood	60	0.85	0.90	0.67	0.96	0.89
	45	1.00	0.96	0.63	1.00	0.96
	30	1.00	0.99	0.43	1.00	0.99

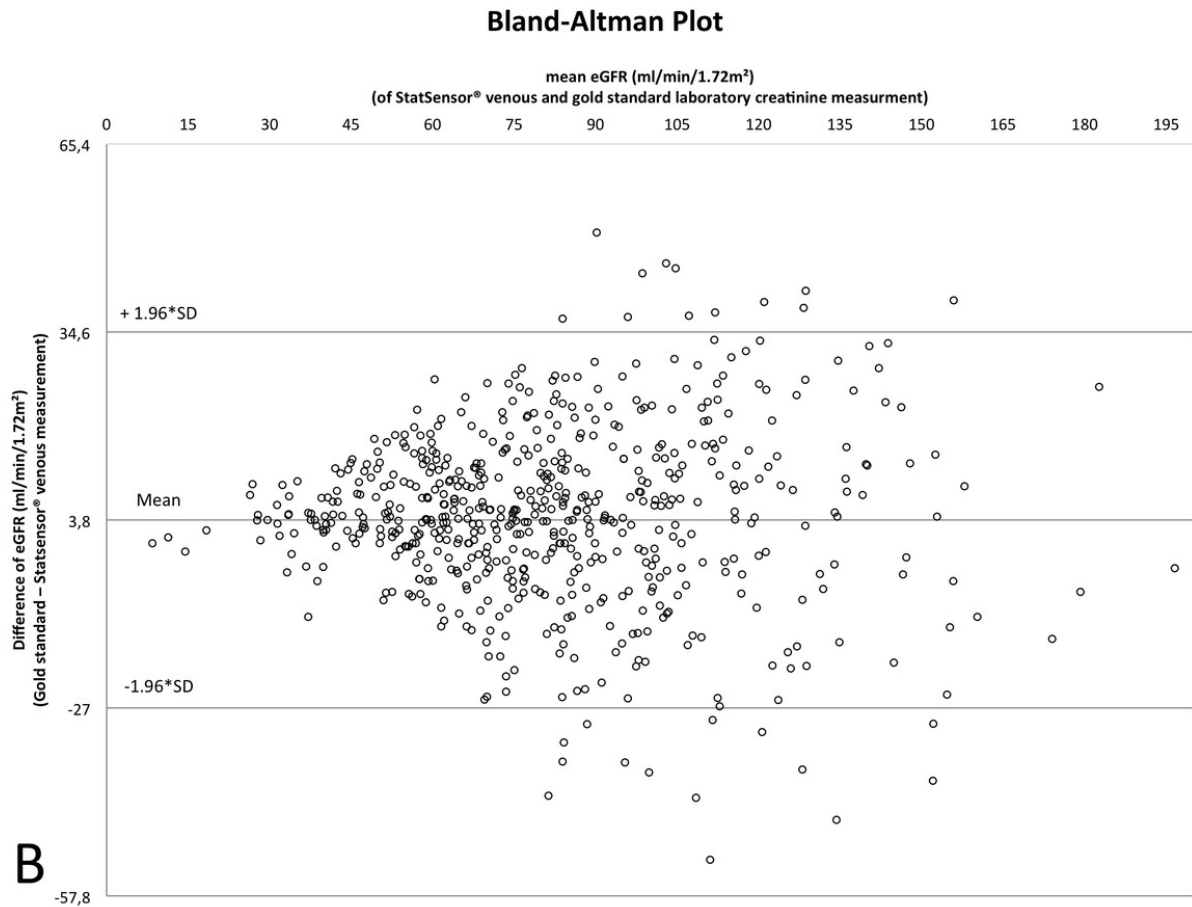
It shows a 100% sensitivity for the detection of patients with an eGFR  $< 30$  and  $< 45$  ml/min/1.73m<sup>2</sup>, while sensitivity was lower if a cut-off eGFR of 60 ml/min/1.73m<sup>2</sup> was chosen. Negative predictive value was  $> 96\%$  for all three cut-off eGFR values, for capillary as well as venous blood analysis. Specificity ranged from 87% to 99%, depending on the eGFR cut-off value. Positive predictive values varied between 40% and 67%.

Images for this section:



**Fig. 1:** Agreement plot of gold standard laboratory and venous StatSensor® eGFR measurements.

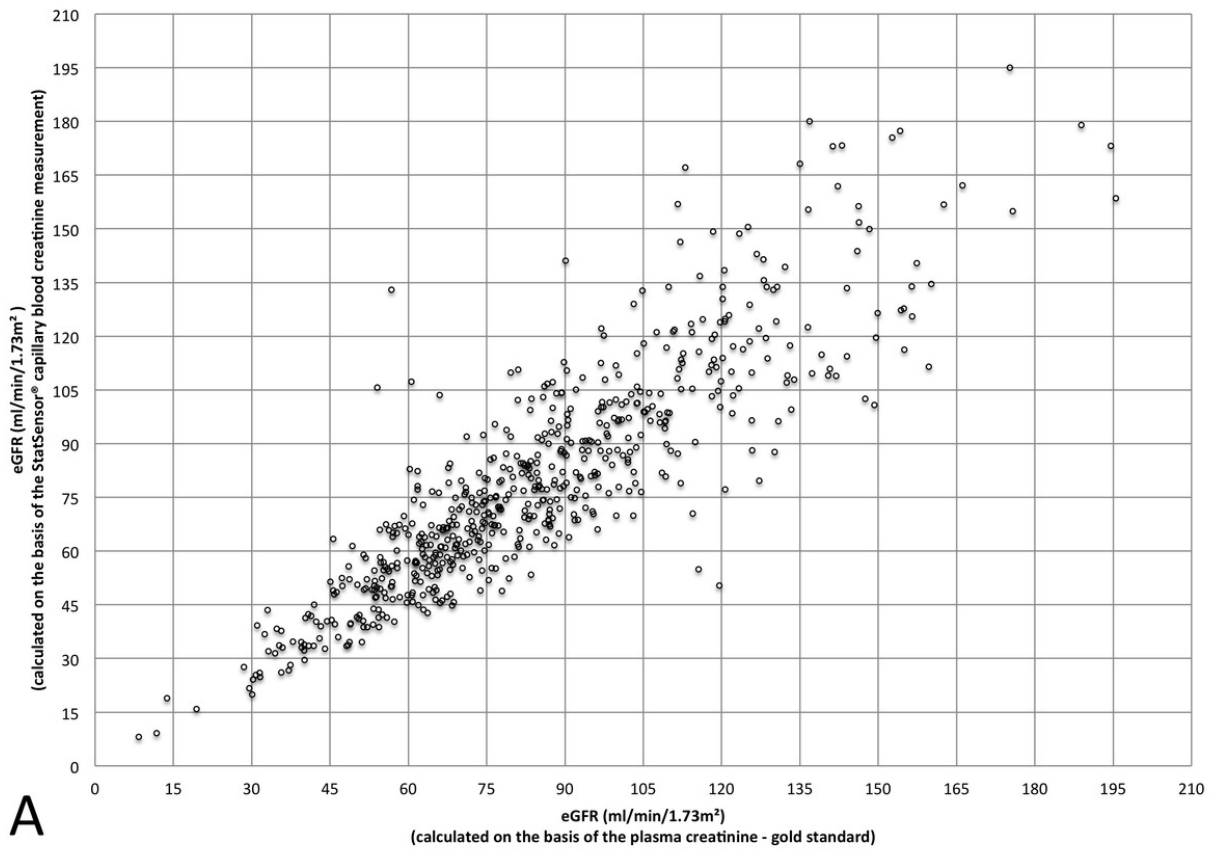
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**Fig. 2:** Bland Altman plot of gold standard laboratory and venous StatSensor® eGFR measurements.

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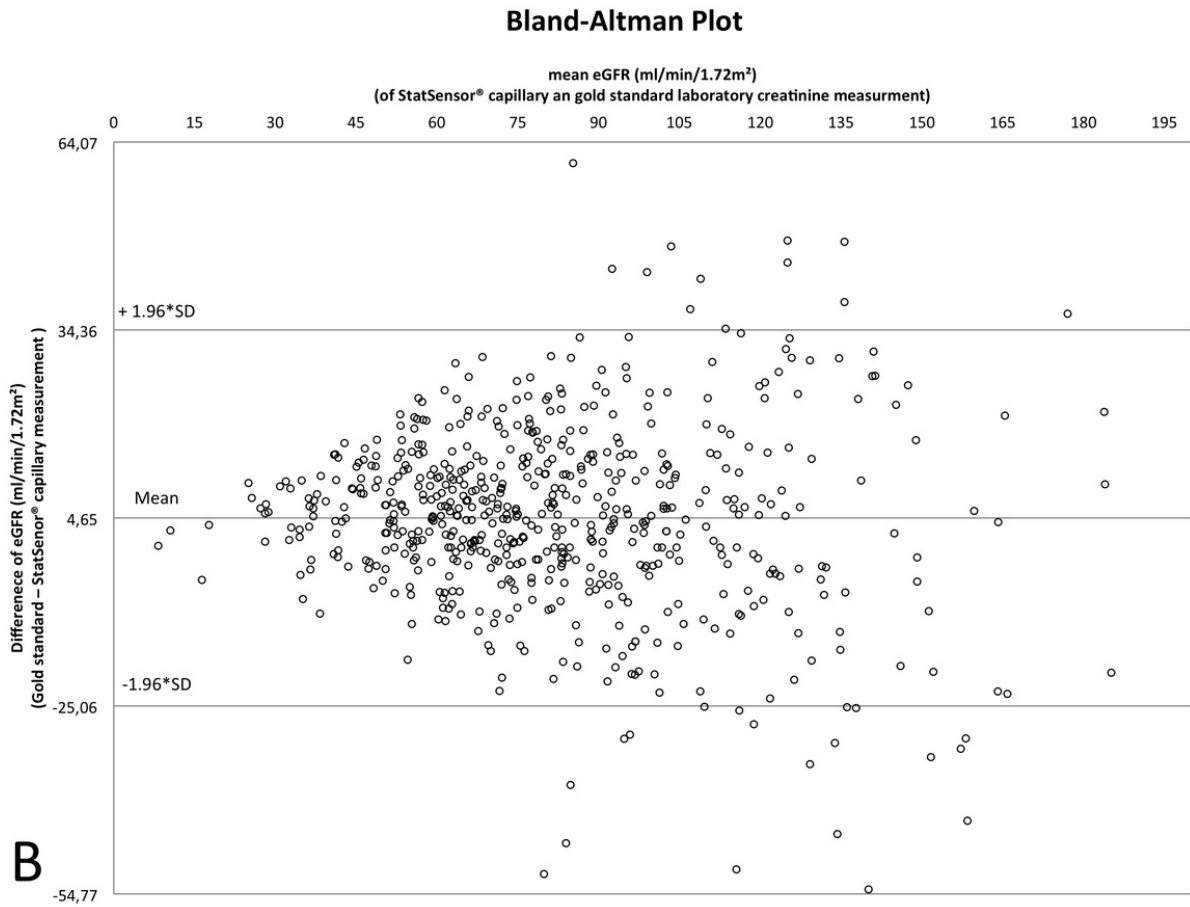
### Agreement Plot



A

**Fig. 3:** Agreement plot of gold standard laboratory and capillary StatSensor® eGFR measurements.

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**Fig. 4:** Bland Altman plot of gold standard laboratory and capillary StatSensor® eGFR measurements.

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## Conclusion

The StatSensor® creatinine meter is a reliable tool in the screening for patients with renal dysfunction with high negative predictive values. Due to low positive predictive values, caution should be exercised in case of positive results, which should be validated by standard laboratory measurement.

## References

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