Analytical performance of the Minicare cTnI Point-of-Care assay

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Introduction

For point-of-care (POC) testing to add value in the clinical setting, analytical performance is very important. In this poster we will present analytical performance data of the cardiac Troponin I (cTnI) on the Philips Minicare Acute.

Applications for this POC system are foreseen in the emergency department where time is of the essence. The first test under development on the Minicare Acute is a cTnI assay with a turn-around time of less than 10 minutes. Analytical studies to verify the final configuration of the cTnI assay on the Minicare Acute system were performed based on guidance from the relevant CLSI documents.

* In development. Not currently available for sale

Increasingly POC systems are used to perform a measurement right next to the patient to reduce the turn-around-time. One of the issues with the current generation of cTn POC tests is that they typically have a lower analytical performance compared to the central lab systems. As a consequence precise quantitation at the clinically relevant 99th percentile Upper Reference Limit (URL) value is not always possible. The Minicare Acute has been designed to have a precision at the clinical cut-off that will enable clinical decision making on the spot.

Methods

Analytical performance studies were performed to verify the performance of the Minicare cTnI assay. The verification data provide the preliminary analytical performance data on the Minicare cTnI assay. The final product specifications will be determined during the validation of the analytical performance data on the Minicare cTnI assay. In particular the following performance characteristics were analyzed:

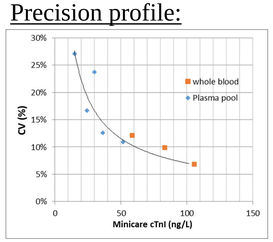
- Analytical sensitivity (Limit of Blank, (LOB) , Limit of Detection, (LOD) , Limit of Quantification (LOQ)
- Precision profile in the clinically relevant concentration range (around the estimated 99th URL)
- Method comparison with a laboratory system
- Sample type comparison (performance in Li-heparin venous whole blood and capillary whole blood)

Results

Analytical sensitivity:

LOB, LOD and LOQ for the Minicare cTnI assay were established in accordance with CLSI document EP17-A2. The resulting LOB was 1 ng/L, LoD was 6 ng/L and the LoQ at 20% CV was 39 ng/L.

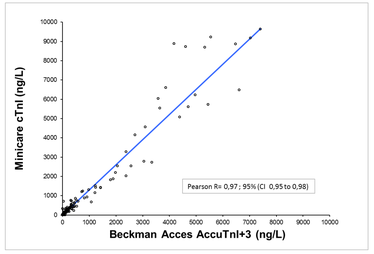
Precision profile:



To determine the precision profile in the clinically relevant range, 5 low cTnI concentrated plasma samples were analyzed. Per sample, 8 replicates are measured on each test day, for 5 days, distributed over 4 analyzers. The plasma precision was repeated in a limited study using spiked whole blood during one day. The fitted concentration for 20% CV is 26 ng/L, for 10% CV the fitted concentration was ~60 ng/L.

Results (continued)

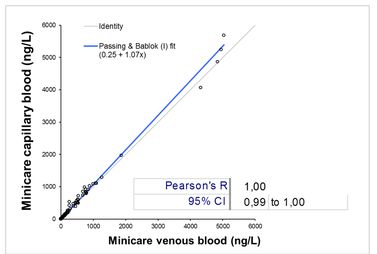
Method comparison:

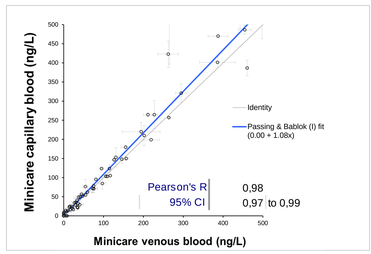


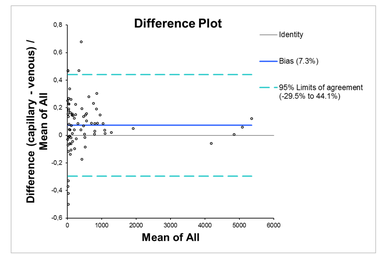
The Minicare cTnI assay and the reference laboratory system, Beckman Access cTnI+3, were compared with a Passing and Bablok regression and a Pearson correlation. The regression of the Minicare cTnI assay versus Beckman Access cTnI+3 assay was -13.05 + 1.38x.
The correlation between the 2 systems was good: over all measurements (n=140) the Pearson correlation coefficient of the Minicare cTnI assay versus Beckman Access cTnI+3 assay was R=0.97 (95% CI: 0.95–0.98.)

Sample comparison:

The correlation between the capillary and venous whole blood sample was very good. Over all measurements (n=87), with cTnI values covering 0-6000 ng/L, a correlation coefficient of R=1.00 and a slope of 1.07 (95%CI:1.04-1.10) were found. In the lower range of cTnI concentrations below 500 ng/l, a similar strong correlation was observed with a correlation coefficient of R=0.98 (n=65) and a slope of 1.08 (95%CI: 1.03-1.14).







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Conclusions

We present the preliminary analytical performance results to verify the Minicare cTnI assay. The study shows the potential of the Philips Minicare Acute to accurately measure cTnI values near the patient with a turn-around-time of less than 10 minutes in the emergency department for patients with suspicion of myocardial infarction. POC tests with such characteristics may reduce length of stay at the emergency department.

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