



Evaluation of Alternative Sample Types for Point of Care Troponin I Testing

A Fortunato, G Soffiati, G Secco



Laboratorio di Chimica Clinica ed Ematologia, Ospedale S.Bortolo, Vicenza, Italy.

Introduction

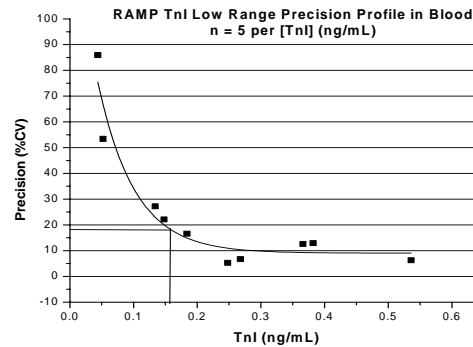
- Commercial TnI assays lack harmonization and normal reference range studies are required to establish appropriate cut-offs.
- Laboratory TnI assays use plasma or serum samples while Point of Care (POC) tests use anticoagulated whole blood.
- Use of whole blood samples for POC precludes storing samples frozen for future analysis.
- This study evaluated the performance of the RAMP POC EDTA whole blood TnI assay versus the Siemens Advia Centaur Ultra Sensitive TnI assay.

Methods and Materials

- EDTA whole blood samples were collected from 100 subjects without cardiac symptoms to determine the 99th percentile cut-off for the RAMP TnI Assay.
- EDTA and heparinized blood samples were collected from patients where TnI testing was clinically indicated.
- n=46 samples were compared on the RAMP TnI assay versus the Centaur Ultra Sensitive TnI assay.
- Both EDTA whole blood samples and heparinized plasma samples were analyzed on the RAMP system and compared with heparinized plasma on the Centaur.
- RAMP TnI labeling indicates the use of EDTA whole blood only.
 - The use of other anticoagulants or plasma is precluded.

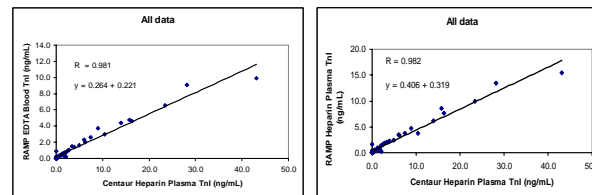
Results

The normal range cut-off on RAMP for EDTA whole blood was determined to be 0.16 ng/mL. The CV at the 99th percentile (0.16 ng/mL) was 18%.



Results

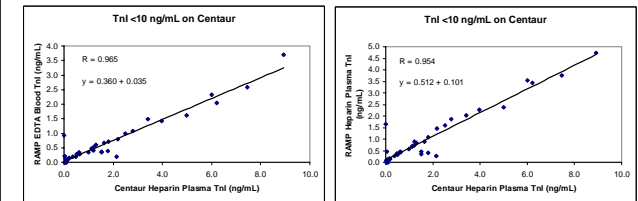
Regression analysis of RAMP vs Centaur for all samples.



RAMP TnI showed excellent correlation with the Centaur TnI for both EDTA whole blood ($r = 0.981$, one outlier excluded) and heparinized plasma ($r = 0.982$).

Results

Regression analysis of RAMP vs Centaur for samples <10 ng/mL TnI on Centaur.



Strong correlation was maintained for whole blood ($r = 0.965$) and plasma ($r = 0.954$) when samples with <10 ng/mL TnI by Centaur were compared using both test methods ($n = 31$).

RAMP heparin plasma versus RAMP EDTA whole blood showed a correlation coefficient of 0.996 and slope of 1.53.

Conclusions

- The RAMP POC TnI Assay correlates strongly with the Siemens Advia Centaur Ultra Sensitive laboratory TnI assay.
- Using an appropriately defined cut-off, the RAMP TnI assay provides accurate diagnostic results in less than 20 minutes.
- While not included in the manufacturer's claims for use, heparin plasma samples can be run on RAMP.
 - Differences in results, as shown in this study, must be taken into account if plasma is used.