CARMEN: The Alere Triage Cardiac Panel Whole Blood and Plasma Equivalence Study on TriageTrue

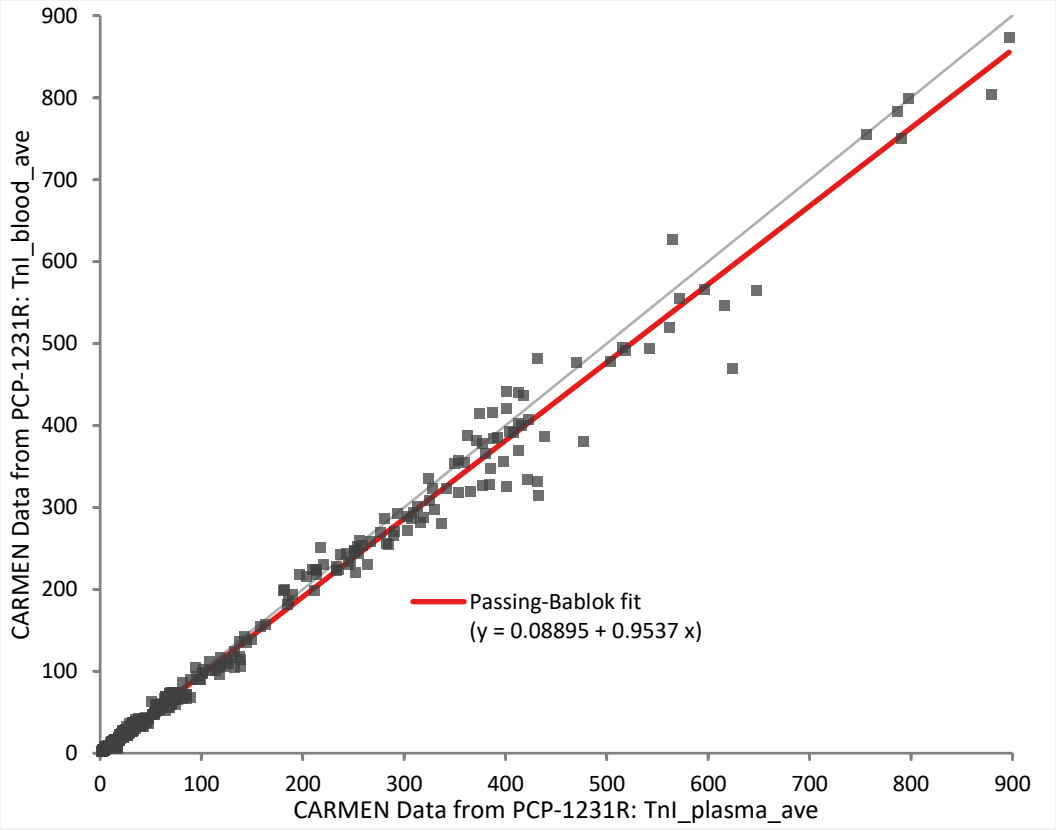
Goal: Determine analytical performance of TRUE in the intended use setting

- 5 sites (PI's):
  - Suny Stony Brook (Singer)
  - Massachusetts General (Nagureny)
  - University of Maryland (deFilippi/Christenson)
  - Minneapolis Medial Research Foundation (Apple)
  - Vanderbilt (Barrett)
- Each site has 6 meters to run up to 6 device lots
- 80 subjects were included in the study
- Each device lot run on one meter, using precision pipette
- Same subject run on all device lots in WB (N=2, up to 4), and PL (N=2, up to 4):
  - B/P bias
  - EC rate
  - Lot to lot recovery
- Study draws enough sample to carry out higher N testing for precision measurements, but insufficient device number at this round of testing
- Users record results reported by meter as well as provide weekly trace downloads from meter

QUIDEL®

Whole Blood vs Plasma bias for samples compared from same individual blood draws – All Data

CARMEN Patient Data April 2018 – July 2018



TriageTrue Package Insert whole blood/plasma claim

From the Triage True CE Mark PI:
Whole Blood / Plasma Bias Method Comparison

A study to determine the bias between whole blood and plasma specimens from the same patient sample was developed across 5 clinical sites running fresh samples. Matched whole blood and plasma clinical specimens from the same donors were tested in duplicate with 6 lots of test devices. Passing-Bablok regression analysis yielded correlation coefficients of 0.994 or greater for all populations considered, with mean bias values no greater in magnitude than -5.6% at the 99th URL decision point. This corresponds to an average recovery of whole blood values that are 5.6% lower than plasma values obtained from the same donor. The use of one sample type (either whole blood or plasma) is recommended for troponin analysis when measuring serial samples from the same patient.

Population	N (Subjects)	Slope (95% CI)	Intercept (95% CI)	Pearson r-value	Mean Bias (TnI Concentration at 99th % URLs)
Overall	80	0.954 ng/L (0.945 - 0.963 ng/L)	0.089 ng/L (-0.202 - 0.344 ng/L)	0.995	-4.2% (20.5 ng/L)
Female	28	0.947 ng/L (0.929 - 0.962 ng/L)	-0.040 ng/L (-0.404 - 0.509 ng/L)	0.994	-5.6% (14.4 ng/L)
Male	52	0.958 ng/L (0.947 - 0.969 ng/L)	0.111 ng/L (-0.289 - 0.445 ng/L)	0.995	-3.8% (25.7 ng/L)

Extra

Whole Blood vs Plasma bias for samples compared from same individual blood draws – Samples ≤ 20 ng/L

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