RAMP® Reader Movement Study

Cardiovascular - RAMP® Troponin I

About the RAMP® Reader

The RAMP® Reader instrument together with RAMP® tests make up the RAMP® Platform, a quantitative immunochromatographic system for the determination of cardiac markers in EDTA whole blood. The RAMP® Platform provides healthcare professionals with a choice of cardiac markers to optimize clinical diagnosis through objective, rapid test results with an average time to result of ~15 minutes.

The RAMP® Reader is light-weight and portable with a rechargeable on-board battery. It is designed for use both in the clinical lab, and in locations such as doctor's offices, hospitals, emergency rooms and on-site emergency response.

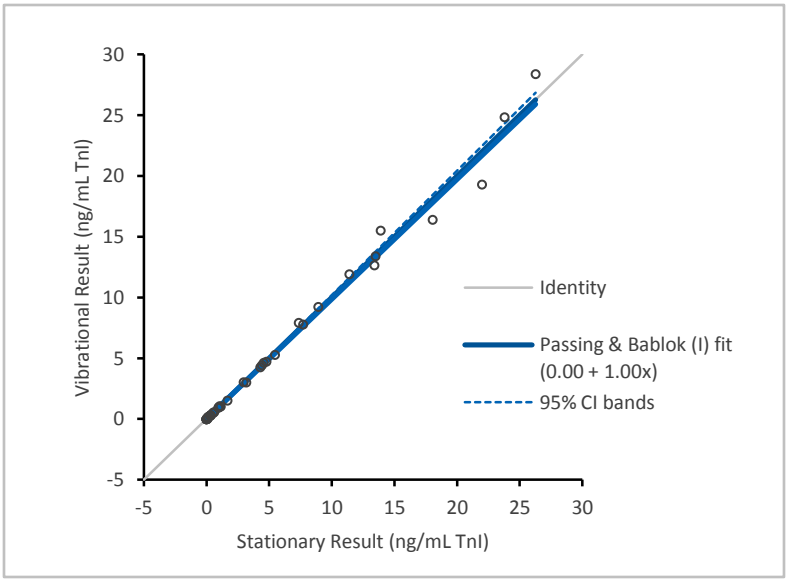
Movement Study

The portable nature of the RAMP® Reader makes it ideal for use in emergency response vehicles, where RAMP® Biodefense tests are already in widespread use. The following study was performed to verify that the vibration of an idling or moving vehicle does not inhibit the development of the RAMP® Troponin I test and, as such, may be used as an aid in diagnosis for acute myocardial infarction in emergency vehicles such as ambulances, fire trucks or field units.

A total of 40 clinical patient samples were tested on the RAMP® Troponin I test (Cat. No. C1101) both while the RAMP® Reader was stationary and while the instrument was moving. In order to simulate the motion of a moving vehicle, the RAMP® Reader was placed on an orbital shaking platform for all stages of the test.

Data analyses were performed using the Passing and Bablok regression analysis method described in CLSI guideline *EP09-A3 – Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition*. The data display excellent correlation between the two methods (R^2 = 0.99) with no significant bias across the full assay range, including the medically relevant concentrations 0.10 ng/mL (RAMP® Troponin I 99th Percentile) or 0.30 ng/mL (the clinical cutoff of RAMP® Troponin I in clinical trial).

	Bias	95% CI
Constant	0.00	-0.02 to 0.00
Proportional	1.00	0.99 to 1.02
Decision level	**Bias**	**95% CI**
0.10 ng/mL	0.000	-0.044 to 0.014
0.30 ng/mL	0.000	-0.039 to 0.011



Please contact Response Technical Support for further information.

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