Performance Evaluation of PATHFAST Instrument & Reagents of Mitsubishi Chemical Europe

Evaluation Site: Spain

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Testing of Reproducibility of PATHFAST cTnI

	Laboratory 1	Laboratory 2	Laboratory 3	Laboratory 4
Sample 1				
Mean (ng/mL)	0.715	0.684	0.756*	0.67
Intrassay CV (%)	4.44	4.73	3.55	4.62
Interassay CV (%)	7.01	5.82	9.82	6.26
Sample 2				
Mean (ng/mL)	8.989	8.6	9.84*	8.25
Intrassay CV (%)	3.45	3,22	3.32	2.50
Interassay CV (%)	5.83	5.62	9.97	7.12

*Mean value is significantly different from that of the other laboratories

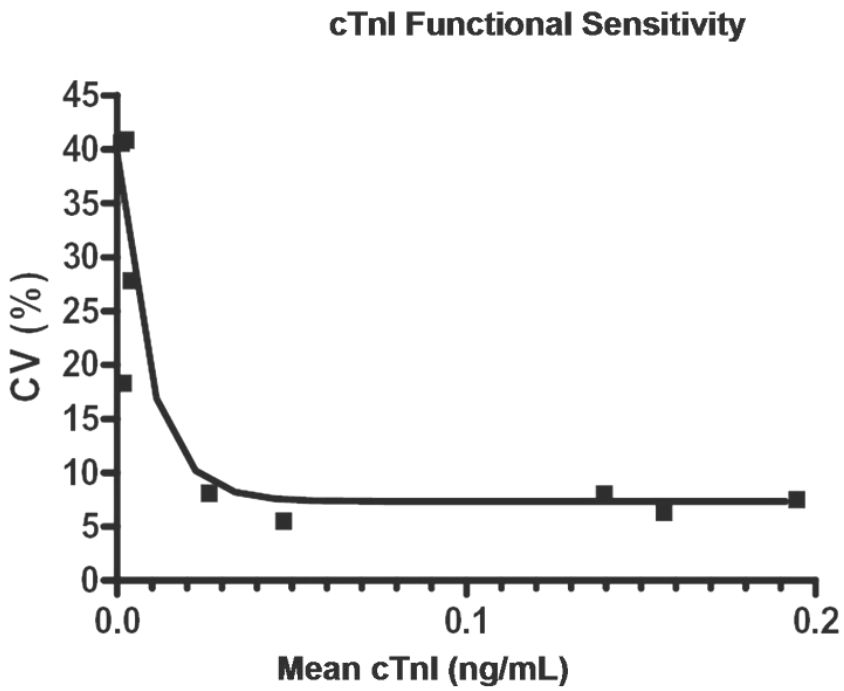
Testing of Analytical Sensitivity of PATHFAST cTnI

	cTnI Analytical sensitivity
Laboratory 1	0.003
Laboratory 2	0.004
Laboratory 3	0.003
Laboratory 4	0.008

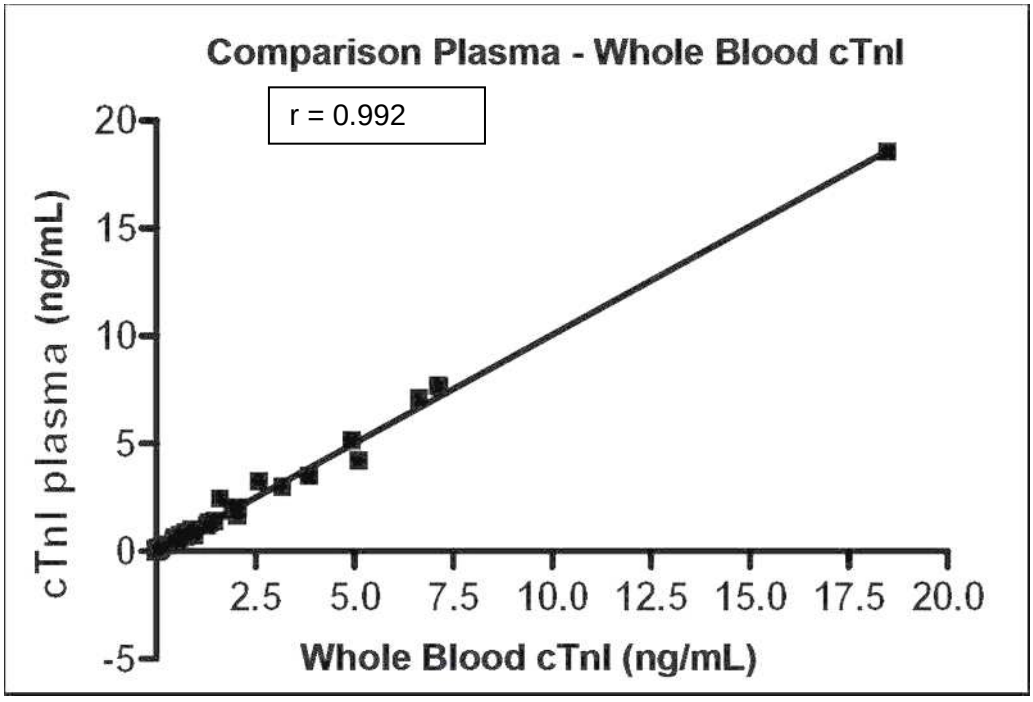
Testing of Reference Range of PATHFAST cTnI

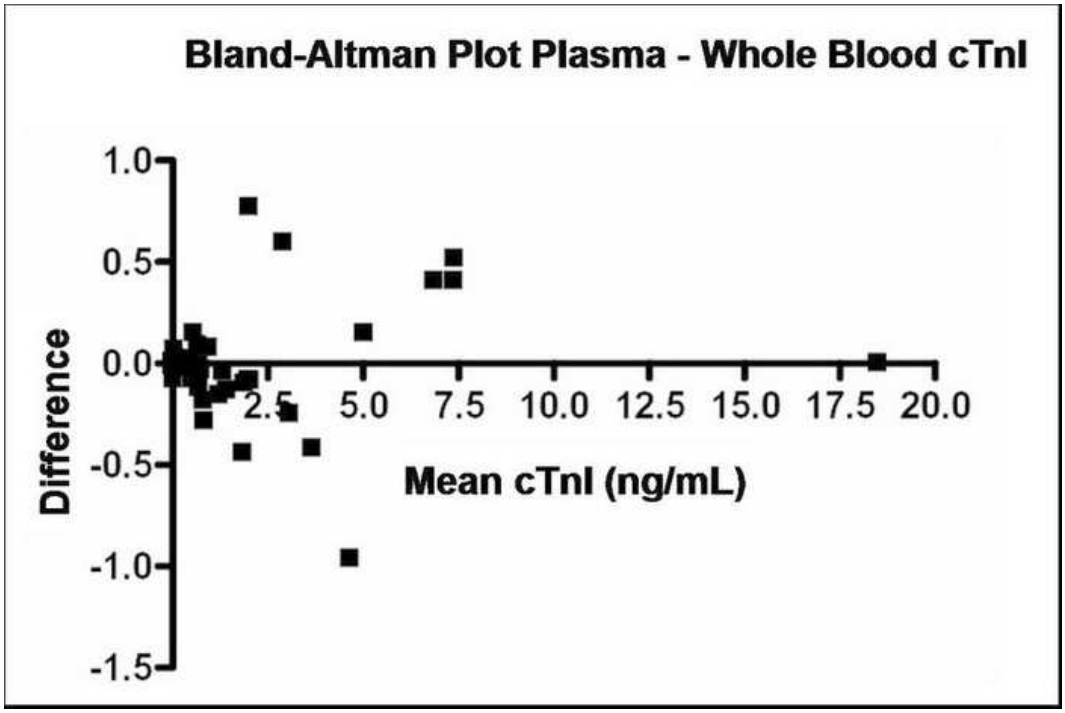
	cTnI 99th percentile of healthy subjects
Laboratory 1	0.009
Laboratory 2	0.006
Laboratory 3	0.018
Laboratory 4	0.009

Testing of Functional Sensitivity of PATHFAST cTnI

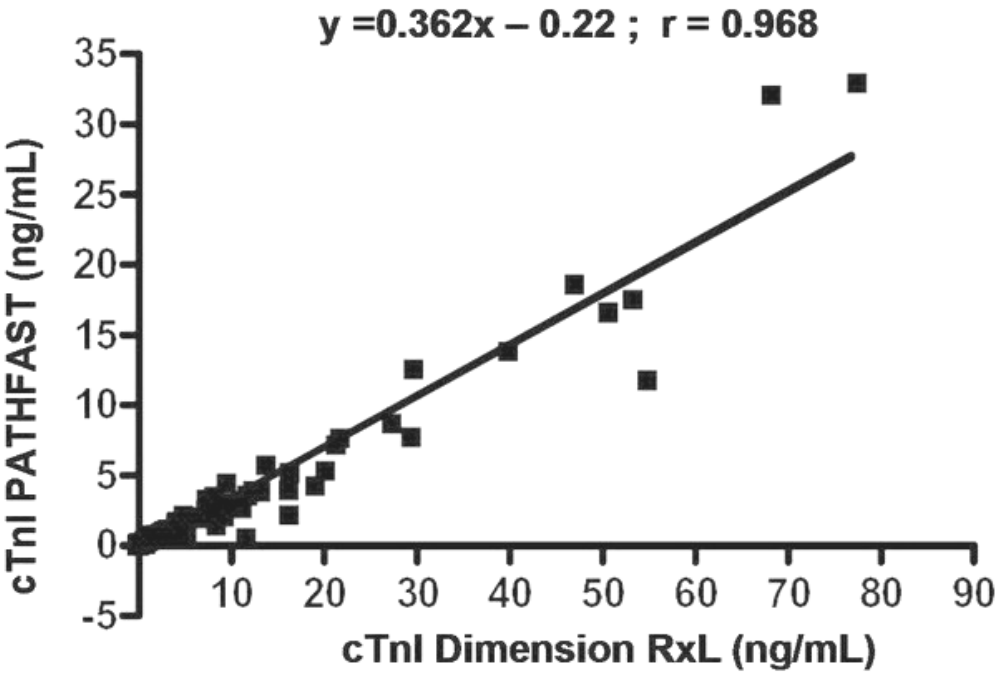


Testing of PATHFAST cTnI in Plasma versus Whole Blood

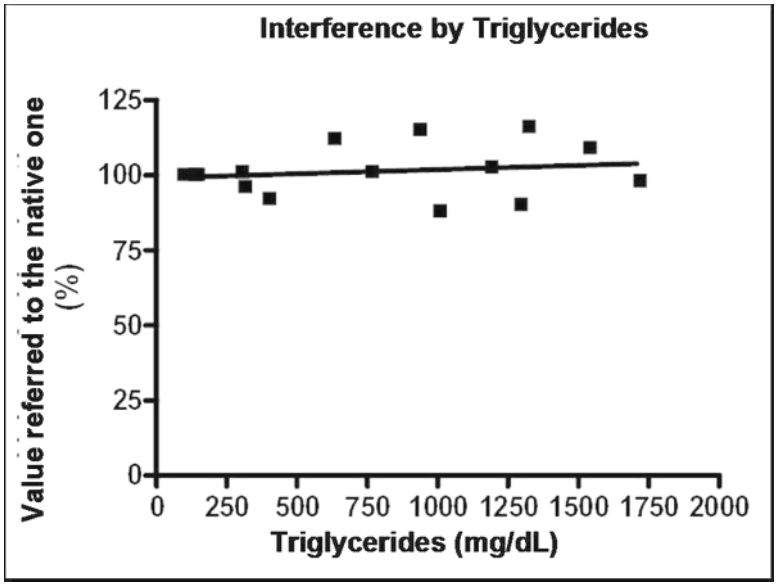


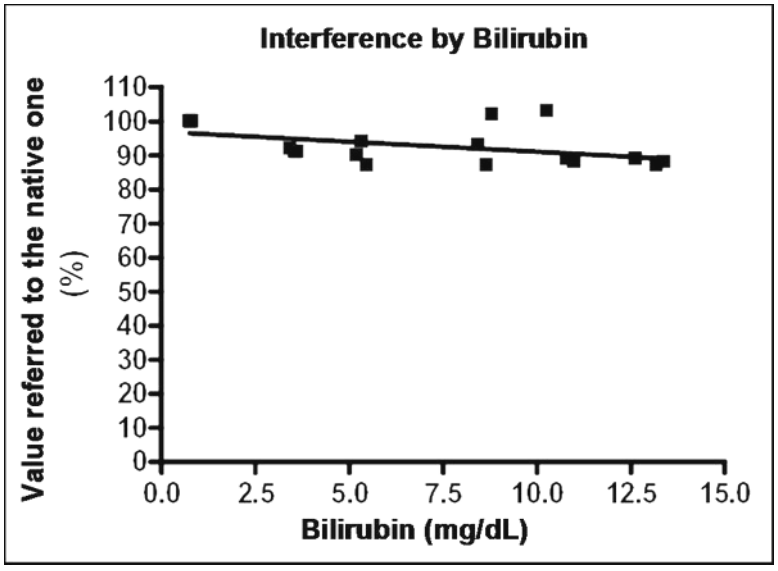


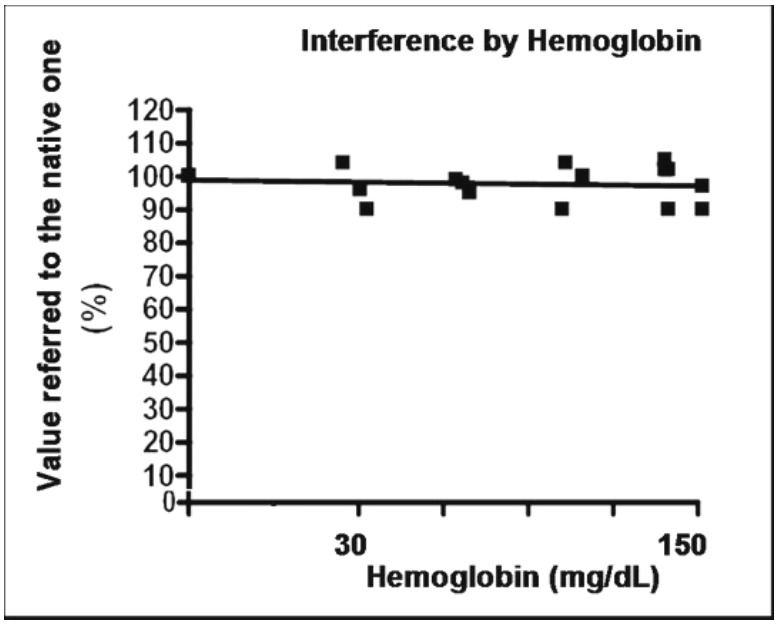
Comparison of cTnI – PATHFAST – Dade Behring Dimension RxL



Testing Possible Interferences (Hyperlipemia, Hyperbilirubinemia, Hemolysis)







Conclusions of the five Spanish investigators

The PATHFAST® is a chemiluminescent enzyme immunoassay analyzer, rapid and compact, that can process plasma and total blood samples. In this study some of its functional characteristics have been evaluated, like the daily variability, the variability day-to-day, the values of reference, the correlation with routine method, the analytical sensitivity, the functional sensitivity, the interferences by lipemy, haemolysis and biirubine and the interferences by other pathologists. The evaluation has been designed as a multicenter study in which have participated the emergency laboratories of four Spanish centres. The parameter chosen to carry out this evaluation was troponine I cardiac (cTnI). The coefficient of daily variation was always inferior to 5% whereas the day-to day has not surpassed 10% in any case. Analytical sensitivity was between 0.003 and 0.008 ng/mL for the four laboratories and the functional sensitivity obtained was 0.025 ng/mL. The correlation coefficient obtained (r) between plasma and total blood was of 0.997 and the analysis of correlation with current method (Dimension, Dade Behring) gave a coefficient of correlation (r) of 0.968. Finally, the tests reveal that the results are not altered by the presence of interferences or of other pathologies. The PATHFAST analyzer has demonstrated to be a trustworthy equipment, precise and easy to handle, with a good practicability for small and average laboratories or for emergencies laboratories.