PATHFAST® MITSUBISHI: THE BIOLOGICAL PATH COMMUTABILITY IN THE ASSAY FOR CARDIAC TROPONIN I (CTNI) IN EMERGENCY USE.

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Summary: The high importance of TAT with the TnI assay requested in emergency unit explains why to make use of blood plasma or use of whole blood in POCT (K3EDTA). The use of heparin or EDTA may cause interferences and this can produce a risk of incorrect classification of clinically important results.

The new enzyme immunoassay method -III generation cTnI assay- on PATHFAST® drove us to evaluate the effect of the biological matrix variation on several cTnI assays.

Method and materials: PATHFAST® Mitsubishi, distributed by Gepa, operates with single use reagent cartridges in a sandwich test format (solid phase). Liquid reagents are sealed individually in small wells that are pinched by the analyser shortly before measuring.

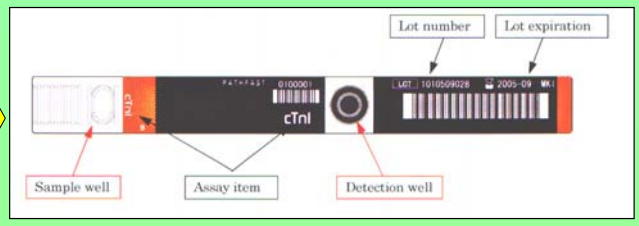
K3 EDTA | Heparin-Li | no additive

Emergency Unit

30 Patients

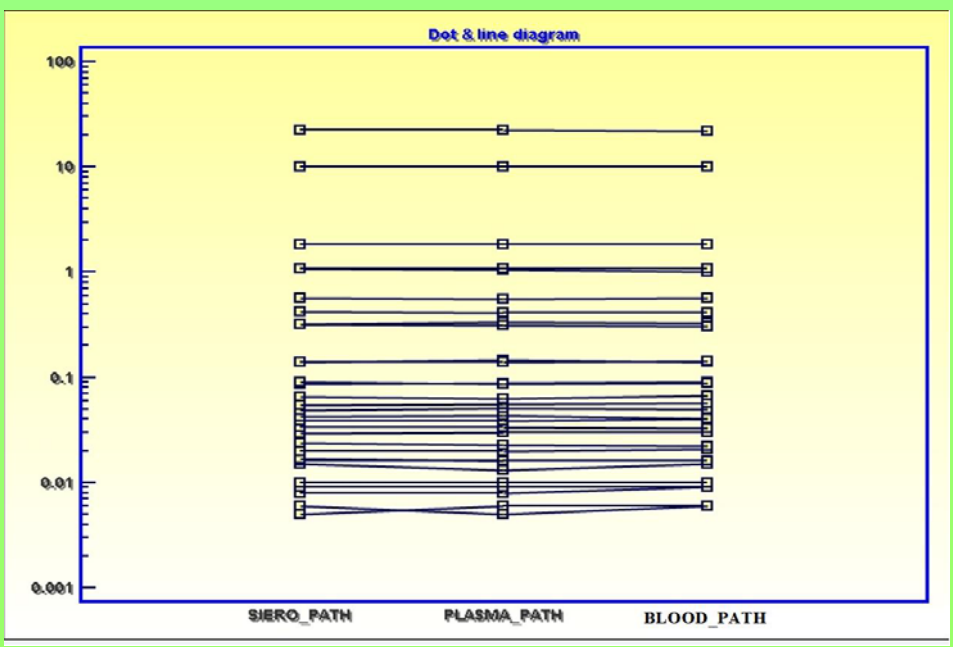
Intensive Care

Cardiac Intensive Care



- Tn I determination with standard method
- Statistic elaboration with Wilcoxon test

Results: The results do not show biological paths influence compared with serum: p:0,47 and p=0,50. The linear regression shows: serum vs plasma samples y=0.006327 + 0.9884x; serum vs whole blood y=0.00007823 + 1.0050x. The graphic below demonstrates results and the trend of the three considered paths.



TROPONIN I SPECIFIC DETERMINATION: INFLUENCE OF HEPARIN

Tosoh AIA 360 TnI	Analyzed Sample Type	Serum and plasma with heparin-Li. EDTA is not provided by the method
	Specification	Evaluation of plasma samples (n.65) **SHOWS A MEAN INCREASE** of 8.41 % in comparison with serum samples (mean difference 0.1935;DS 0.4866; P=0.0021). **Tests run in lab.**
ADVIA Centaur Assay Manual TnI	Analyzed Sample Type	Serum and plasma with heparin-Li. Anticoagulant EDTA is not provided by the method
	Specification	Evaluation of plasma samples (n.112) **SHOWS A MEAN REDUCTION** of 11% in comparison with serum samples (plasma 0.89, r=0.96) as specific manual in house.
Siemens Immuno I Assay Manual TnI	Analyzed Sample Type	Serum and plasma with heparin-Li. Anticoagulant EDTA is not provided by the method
	Specification	Evaluation of plasma samples (n.47) **SHOWS A MEAN REDUCTION** of 10% in comparison with serum samples (plasma 0.90, r=0.99). By Literature of University of Vitalba (MI).
Immunolite Assay Manual TnI	Analyzed Sample Type	Serum, plasma with heparin-Li and EDTA
	Specification	Evaluation of plasma samples (n.47) **SHOWS A MEAN REDUCTION** of 31% in comparison with serum samples (heparin plasma 0.71, r=0.99), (plasma EDTA 0.71, r=0.97). By Literature of University of Vitalba (MI).
PATHFAST MITSUBISHI distributed by Gepa	Analyzed Sample Type	Serum, plasma, whole blood with EDTA and/or heparin.
	Specification	Evaluation of plasma samples (n.30) **SHOWS NO VARIATIONS** in comparison with serum: Plasma heparin 0.98, r=0.99; EDTA Whole blood 0.99; r=0.99. **Tests run in lab.**

Discussion and conclusion: though the small considered survey, the biological path commutability among serum, plasma and whole blood is confirmed and well showed. This will produce important advantages in laboratory practice : a)Correlation among different platforms, b)Reduction of TAT, c)Reduction of risk management correlated to possible wrong classification.