THE III GENERATION TNI ON PATHFAST® MITSUBISHI : THE SAME QUALITY WITH POCT AS IN THE CENTRAL LABORATORY

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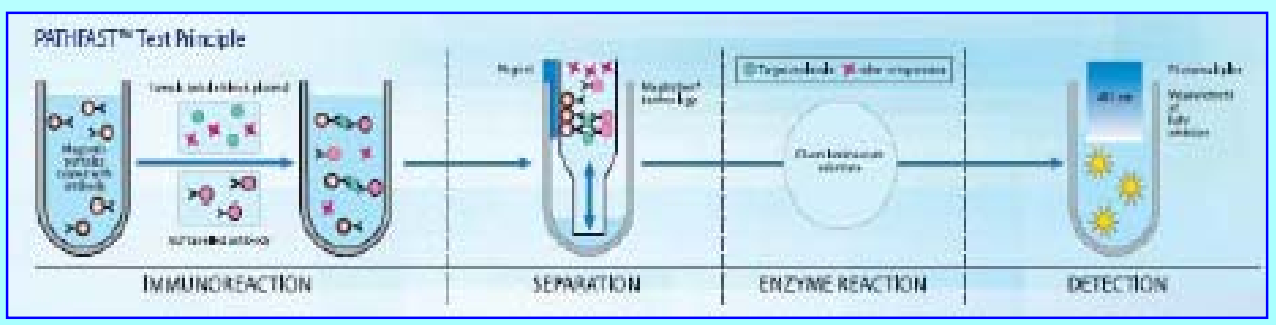
Summary: Troponin T and I are the reference marker of myocardial injury due to their sensibility and specificity . To make best use of Troponin T and I for clinical purposes the IFCC guidelines recommended a total imprecision equal or less than 10% (CV ≤ 10) corresponding to a cut-off at 99th percentile of a reference population. These requirements are very critical for many diagnostic system that have high CV at low Troponin concentrations. The aim of this study is to evaluate the PATHFAST ® system imprecision around the 99th percentile of the reference population.

Materials and methods : PATHFAST® Mitsubishi performance-distributed by Gepa- is base on CLEIA-MAGTRACTION technology and operates with single use reagent cartridges with an antibody sandwich test format . PATHFAST® Mitsubishi provides 6 results in 17'. According the instructions by the producing company analytical sensibility of the system was evaluated (0.001 ug/L). First of all 123 healthy (no myocardial injury) caucasian subjects (89 male an 34 female) of a medium age of 53 years old (39-66) have been evaluated : corresponding 0.030 µg/L at the 99th percentile . Imprecision was calculated on 11 samples with increasing TnI concentration from 0.001 to 0.066 µg/L. The calculation of graphic was executed by Medcalc.



11 patients

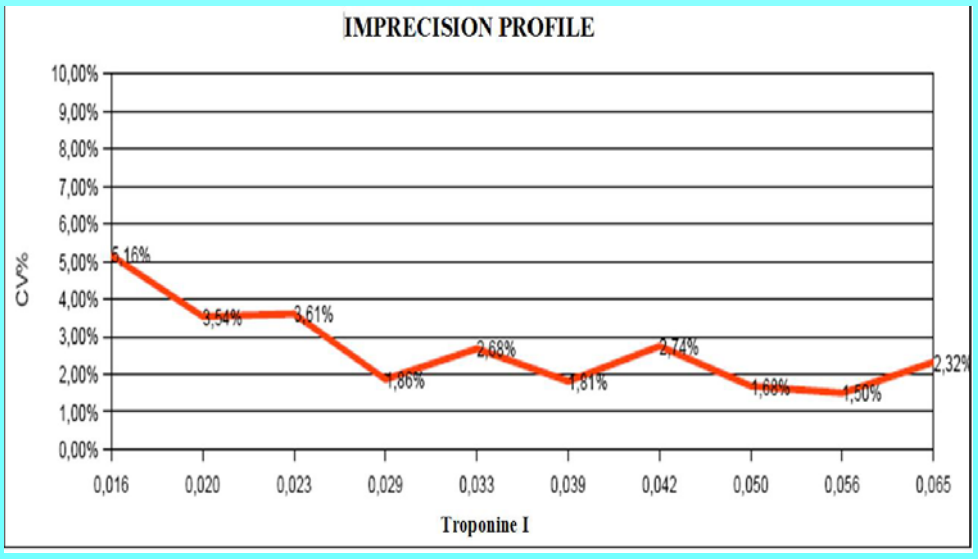
with negative value (0,001-0,020 ug/L)

around cut-off (0,023 - 0,039ug/L)

with feasible positive value (0,042 a 0,066 ug/L)

Result: Test showed an optimal analytical sensibility (0.001 ug/ml) and the imprecision profile is very well covered by the IFCC guidelines at 99th percentile with a CV ≤ 2.1%: For all considered TropI concentrations CV was always less than 5.1% (CV ≤ 5.1% see table and graphic).

	Troponin I	Selected samples repeated for 5 times							
Samples	PATHFAST	run 1	run 2	run 3	run 4	run 5	Mean	DS	CV%
1	Negative	0.001	0.001	0.001	0.001	0.001	0.001	0.000	0.00%
2		0.017	0.016	0.015	0.017	0.016	0.016	0.001	5.16%
3		0.020	0.020	0.019	0.020	0.021	0.020	0.001	3.54%
4	Attention Value	0.024	0.023	0.023	0.024	0.022	0.023	0.001	3.61%
5		0.029	0.030	0.029	0.029	0.030	0.029	0.001	1.86%
6		0.034	0.034	0.032	0.034	0.033	0.033	0.001	2.68%
7		0.039	0.039	0.038	0.039	0.040	0.039	0.001	1.81%
8	Decision Value	0.042	0.043	0.041	0.042	0.040	0.042	0.001	2.74%
9		0.049	0.051	0.050	0.049	0.050	0.050	0.001	1.68%
10		0.055	0.056	0.056	0.055	0.057	0.056	0.001	1.50%
11		0.066	0.063	0.065	0.066	0.067	0.065	0.002	2.32%



Discussion and conclusions:

From the results it is evident that:

- The excellent performance of analytical sensitivity, the requested precision of TnI at 99° % is beyond the IFCC guideline;
- The excellent analytical sensitivity and precision grant a very low cut-off, essential condition for a better diagnostic sensitivity
- Test is quickly and easy to use with reduced dimension, cartridges "all in one" without any additional preparation; this results makes PATHFAST® particularly suitable as well as for centrallab use as for POCT use.