PATHFAST cTnI Meets the Criteria for High-Sensitivity Troponin Assays

E. Spanuth[1], R. Thomae [2] , E. Giannitsis [3]

[1)]DIAneering®, Diagnostics Engineering & Research GmbH, Heidelberg, Germany, [2)] Mitsubishi Chemical Europe, Düsseldorf, Germany, [3)] Dept. of Medicine III, Div. of Cardiology, University of Heidelberg, Heidelberg, Germany

Background

Contemporary available point-of-care assays for troponin cannot provide the analytical and diagnostic accuracy required for "highly-sensitivity" assays by international guidelines. The PATHFAST cTnI POC assay has shown promising analytical validity.

Aim of the study

To examine whether the PATHFASTcTnI could be classified "highly-sensitive".

Methods

Control group: 119 healthy individuals (60 men and 59 women, 21-69 years old, median 42 years).
Patient group: cTnI (PATHFAST) and cTnT (cobas® hs-cTnT) were compared in 181 patients admitted to the chest pain unit at presentation, 3 and 6 hours later. The results were related to the discharge diagnoses.

Results

Tab. 1: PATHFAST cTnI (ng/L) in healthy individuals (control group)

	n	Mean	IQR	Lowest value	Highest value
All	119	2.06	0.87-1.86	0.37	17.2
Men	60	2.82	1.15-2.64	0.53	17.2
Women	59	1.12	0.70-1.25	0.37	11.2

p < 0.0001

➢**99th percentile:** **16 ng/L** (CLSI C28-A3)
manufacturer recommended: 20.0 ng/L

➢**Quantification:** **66.4%** (**>** LoD (1.0 ng/L) and **<** 99th percentile):
(in 79 of 119 healthy individuals of the control grou

➢**Imprecision:**

cTnI (ng/L)	CV (NCCLS)
2.0	20%
3.0	10%
20.0	5%

➢**Imprecision Profile:**

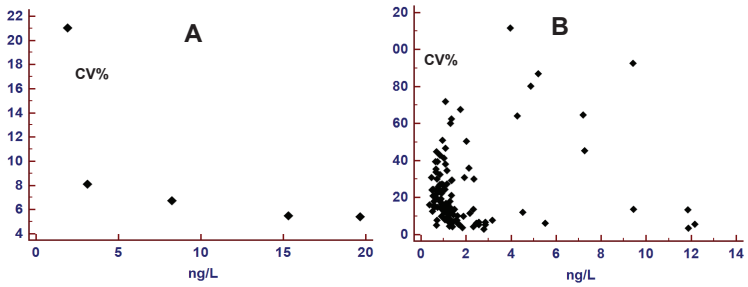

Fig. 1: Imprecision Profile according to NCCLS
A: at 1.93, 3.13, 8.29, 15.32 and 19.66 ng/L
B: CVs from3-fold determination of controls, n=119

Tab. 2: PATHFAST cTnI in patients with chest pain at presentation (0 h), and after 3 (3 h) and 6 hours (6 h)

	NSTEMI, n=72 Median (IQR)	UAP and NCCP*) Median (IQR)
0 h	46 (34-76)	2.0 (1.0-4.0)
3 h	166 (52-759)	2.0 (2.0-5.0)
6 h	399 (85-1100)	3.0 (2.0-6.0)

***)UAP (unstable angina pectoris), n=80; NCCP (non cardiac chest pain), n=29**

Tab. 3: Results of ROC analysis for diagnosis of NSTEMI

	PATHFAST cTnI			hs-cTnT (cobas)		
	AUC	SENS (%)	SPEC (%)	AUC	SENS (%)	SPEC (%)
0 h	0.919	83	93	0.923	77	95
3 h	0.962	93	96	0.964	92	97
6 h	0.958	91	94	0.969	94	97

Absolute change of cTnI:

	cTnI < URL at admission (n=16)			cTnI ≥ URL at admission (n=56)		
	Median	Change		Median	Change	
0h	0,0050	*(pg/ml)*	*(%)*	0.099	*(pg/ml)*	*(%)*
3h	0,0405	**0.036**	**710**	0.328	**0.229**	**231**
6h	0,141	**0.101**	**248**	0.524	**0.196**	**59.8**

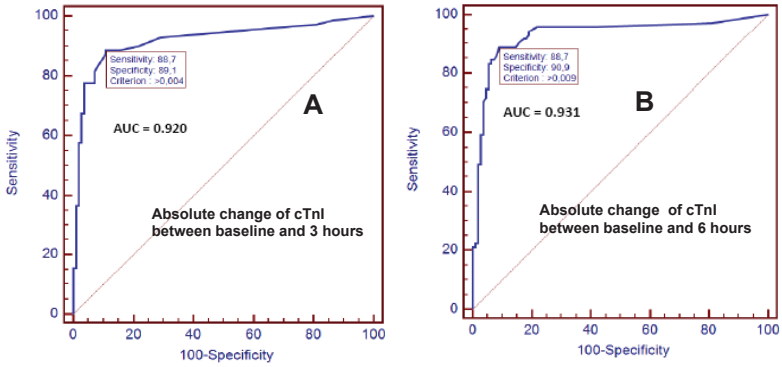

Fig. 2: ROC curve of absolute change for NSTEMI
A: between baseline and 3 hours; B: between baseline and 6 hours

Conclusion

PATHFAST cTnI meets the criteria for high-sensitive cTn assays:

- **Imprecision CV at the 99th percentile: 5%** *(<10%)*
- **Quantification in healthy individuals: 66.4%** *(>50%)*
- **Complete concordance with cobas hs-cTnT for the diagnosis of NSTEMI**
- **Absolute changes of cTnI values over time in NSTEMI patients > 30%**