Performance Evaluation of PATHFAST Instrument & Reagents of Mitsubishi Chemical Europe

Evaluation Site: Poland

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Table 1. *Intra-Assay Reproducibility for Troponin I and Myoglobin*

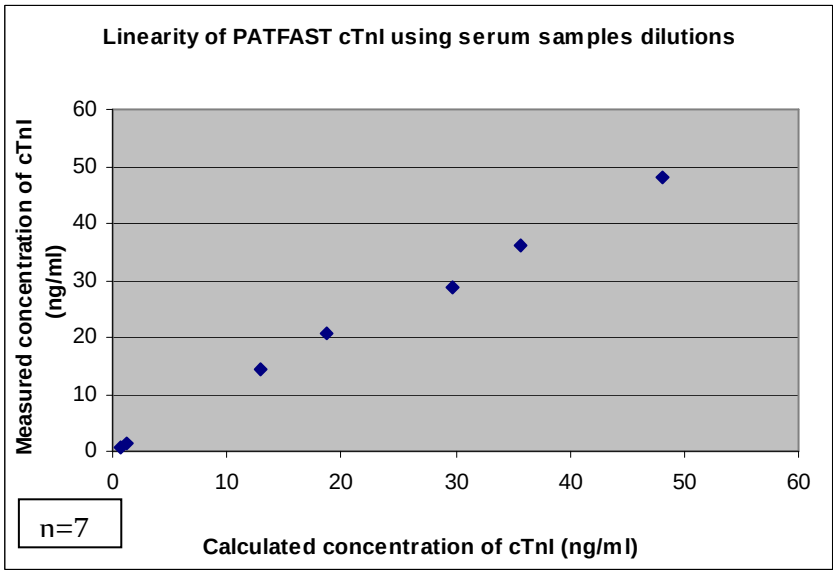
	cTnI			**Mioglobin**	
No	serum 1	serum 2	Nr	serum 1	serum 2
1	0.098	21.7	1	142	14.5
2	0.090	22.0	2	138	13.1
3	0.093	21.8	3	136	13.2
4	0.085	22.7	4	142	13.7
5	0.083	21.2	5	150	14.8
6	0.088	21.0	6	131	14.8
7	0.094	21.8	7	145	13.9
8	0.094	22.3	8	148	14.1
9	0.090	21.7	9	147	13.6
10	0.087	22.2	10	140	14.7
11	0.088	22.6	11	135	14.7
12	0.091	21.5	12	144	13.9
mean	0.090	21.87	mean	141.5	14.08
CV (%)	4.69	2.36	CV (%)	4,04	4.36
SD	0.0042	0.172	SD	5,73	0.615
min	0.083	21.0	min	131	13.1
max	0.098	22.7	max	148	14.8

Table 2. *Inter-Assay reproducibility for Troponin I and Myoglobin*

No	cTnI		MYO	
	serum 1	serum 2	serum 1	serum 2
1	0.527	5.29	36.4	155
2	0.531	4.71	36.5	150
3	0.533	5.40	37.6	161
4	0.536	5.90	40.1	158
5	0.536	5.09	40.8	156
6	0.490	5.00	35.6	151
7	0.509	4.59	37.9	162
8	0.534	4.53	35.5	180
9	0.527	5.29	38.8	154
10	0.581	5.27	29.6	172
mean	0.530	5.107	36.88	159.9
CV (%)	4.58	8.19	8.46	5.63
SD	0.0243	0.419	3.125	9.49
min	0.490	4.53	29.6	150
max	0.581	5.90	40.8	172

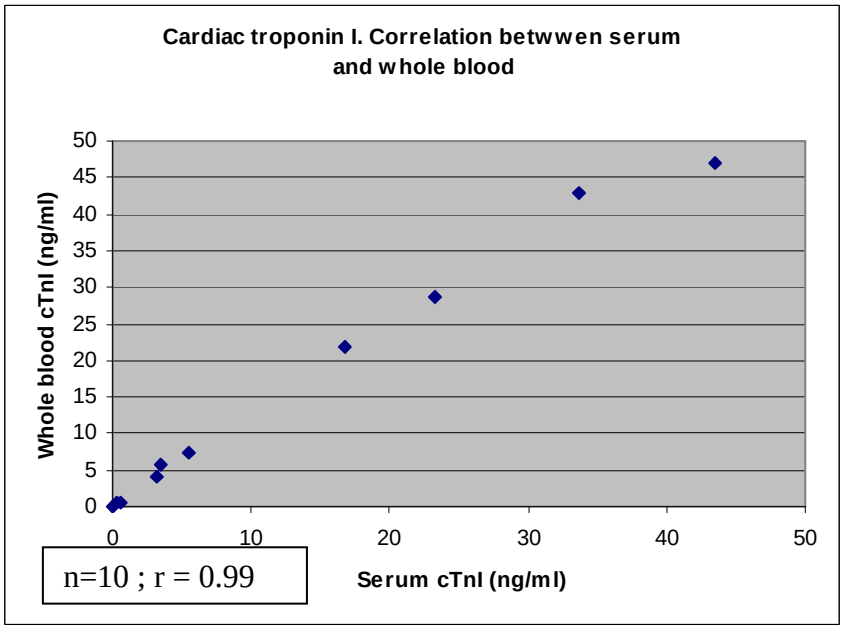
Linearity of cTnI determination by PATHFAST

Dilution	cTnI (ng/mL)			
	Measured concentration			Calculated concentration
	1	2	mean	
200x	0.745	0.563	**0.654**	**0.72**
100x	1.27	1.12	**1.19**	**1.44**
10x	14.4	11.6	**13.00**	**14.41**
7x	20.5	16.8	**18.65**	**20.58**
5x	31.9	27.6	**29.75**	**28.81**
4x	38.3	33.0	**35.65**	**36.02**
3x	49.5	46.7	**48.03**	**48.03**



Correlation of cTnI measurement in serum versus whole blood

cardiac Troponin I		
Sample no.	Serum	Whole blood
1	23.3	28.8
2	33.6	42.9
3	3.53	5.82
4	5.52	7.27
5	43.5	46.9
6	16.8	21.9
7	0.587	0.544
8	0.005	0.004
9	3.25	4.15
10	0.35	0.42



Correlation of cTnI determination between two different analytical systems:

1. **Laboratory analyzer Dade Behring Dimension X-PAND**
2. **POCT analyzer PATHFAST**

cTnI					
No.	cTnI X-Pand	cTnI PATHFAST	No.	cTnI X-Pand	cTnI PATHFAST
1	7.75	2.74	16	1.92	0.437
2	0.56	0.098	17	6.61	2.16
3	13.99	6.3	18	10.36	2.89
4	3.71	1.24	19	15.77	1.92
5	8.29	2.92	20	6.67	1.98
6	0.13	0.022	21	45.47	15.6
7	0.13	0.014	22	22.71	6.01
8	0.01	0.002	23	96.96	33.7
9	2.73	0.927	24	48.51	14.1
10	1.8	0.538	25	0.05	0.011
11	0.09	0.001	26	0.25	0.082
12	0.02	0.045	27	2.23	0.545
13	0.05	0.004	28	13.87	5.52
14	0.06	0.014	29	79.94	43.5
15	0.96	0.247	30	5.25	0.678
	n = 30; y = 2.921x + 0.873; r = 0.9916