

SMART Troponin I validation REF ST0230

Date 28.01.2013

1.Purpose:

To establish the reference interval of Eurolyser SMART Troponin I assay Ref ST0230
To establish the performance characteristics by using SMART 700 (700/340) photometer

2.Verification Scope:

Reference interval , performance characteristics

3.Standard/Guidance Document Referenced

Clinical and Laboratory Standards Institute **C28-A3** – Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Third Edition

4.Acceptance Criteria

EP evaluator nonparametric range as the reference interval

5.Materials

Cardiac Troponin I Reagents:

Cardiac Troponin I R1: Lot TIRD105120

Cardiac Troponin I R2: Lot TIRD205120

Cardiac Troponin I Calibrators:

Cardiac Troponin I Calibrator 0: Lot TIRDSS01120A

Cardiac Troponin I Calibrator 1: Lot TIRDS101120A

Cardiac Troponin I Calibrator 2: Lot TIRDS201120A

Cardiac Troponin I Calibrator 3: Lot TIRDS301120A

Cardiac Troponin I Calibrator 4: Lot TIRDS401120A

Cardiac Troponin I Calibrator 5: Lot TIRDS501120A

ProMedDx serum samples

Analyser: SMART 700/340 Serial NoBc14077

To establish the reference interval of the SMART Troponin I assay, serum samples from 192 apparently healthy adults were tested using the same reagent used in the SMART700 system according to CLSI C28-A3 guideline. The individual patient serum samples used for the study were from a certified commercial source, ProMedDx.

The serum samples were from apparently healthy male and female adults aging from 16 years of age to 71 years of age. The samples were tested using Diazyme Cardiac Troponin I on Hitachi 917. The results are summarised below.

1.1 Reference Interval Testing

No	Specimen	ID	Gender	Age	Tropl (ng/ml)
1	PromMedDx	11700591	F	17	0.16
2	PromMedDx	11700636	F	16	0.00
3	PromMedDx	11700761	F	17	0.00
4	PromMedDx	11700806	F	59	0.00
5	PromMedDx	11700825	F	17	0.18
6	PromMedDx	11700895	F	17	0.01
7	PromMedDx	11700896	F	18	0.00
8	PromMedDx	11700898	F	18	0.10
9	PromMedDx	11700914	F	17	0.00
10	PromMedDx	11700918	F	16	0.61
11	PromMedDx	11700929	F	54	0.13
12	PromMedDx	11700978	F	17	0.00
13	PromMedDx	11700985	F	18	0.00
14	PromMedDx	11701016	F	17	0.00
15	PromMedDx	11701070	F	16	0.32
16	PromMedDx	11701074	F	60	0.00
17	PromMedDx	11701136	F	28	0.30
18	PromMedDx	11701156	F	19	0.02
19	PromMedDx	11701176	F	19	1.35
20	PromMedDx	11701203	F	17	0.00
21	PromMedDx	11701250	F	47	0.00
22	PromMedDx	11701393	F	27	0.00
23	PromMedDx	11701394	F	54	0.00
24	PromMedDx	11701757	F	21	0.32
25	PromMedDx	11703328	F	44	0.03
26	PromMedDx	11727192	F	26	0.33
27	PromMedDx	11727205	F	25	0.03
28	PromMedDx	11727207	F	53	0.12
29	PromMedDx	11727208	F	49	0.83
30	PromMedDx	11727209	F	55	0.00
31	PromMedDx	11727210	F	49	0.66
32	PromMedDx	11727211	F	26	0.42
33	PromMedDx	11727214	F	49	0.00
34	PromMedDx	11727216	F	38	0.24

No	Specimen	ID	Gender	Age	TropI (ng/ml)
35	PromMedDx	11727218	F	37	0.00
36	PromMedDx	11727226	F	50	0.00
37	PromMedDx	11727228	F	49	0.00
38	PromMedDx	11727231	F	30	0.00
39	PromMedDx	11727232	F	55	0.00
40	PromMedDx	11727233	F	50	1.27
41	PromMedDx	11727234	F	36	1.95
42	PromMedDx	11727239	F	50	0.00
43	PromMedDx	11727251	F	43	0.58
44	PromMedDx	11727252	F	37	0.18
45	PromMedDx	11727253	F	45	2.45
46	PromMedDx	11727276	F	48	0.00
47	PromMedDx	11727278	F	35	0.00
48	PromMedDx	11727279	F	53	1.06
49	PromMedDx	11727288	F	35	0.27
50	PromMedDx	11727290	F	39	0.07
51	PromMedDx	11727296	F	39	0.34
52	PromMedDx	11727302	F	36	0.87
53	PromMedDx	11727303	F	38	0.00
54	PromMedDx	11727305	F	46	0.00
55	PromMedDx	11727313	F	43	0.04
56	PromMedDx	11727319	F	51	0.00
57	PromMedDx	11727329	F	36	0.69
58	PromMedDx	11727331	F	52	0.12
59	PromMedDx	11727333	F	35	0.00
60	PromMedDx	11727337	F	44	0.00
61	PromMedDx	11727338	F	43	0.18
62	PromMedDx	11727339	F	32	0.30
63	PromMedDx	11727345	F	55	0.11
64	PromMedDx	11727346	F	44	0.34
65	PromMedDx	11727350	F	46	0.56
66	PromMedDx	11727351	F	46	0.06
67	PromMedDx	11727352	F	55	0.60
68	PromMedDx	11727353	F	29	0.33
69	PromMedDx	11727364	F	44	0.66
70	PromMedDx	11727365	F	37	0.00
71	PromMedDx	11727376	F	42	0.00
72	PromMedDx	11727377	F	37	0.01
73	PromMedDx	11727382	F	48	0.12
74	PromMedDx	11727389	F	49	0.85
75	PromMedDx	11727394	F	55	0.00
76	PromMedDx	11727400	F	49	0.82
77	PromMedDx	11727407	F	38	0.48
78	PromMedDx	11727409	F	47	0.06
79	PromMedDx	11727417	F	41	0.21
80	PromMedDx	11727418	F	22	0.52

No	Specimen	ID	Gender	Age	TropI (ng/ml)
81	PromMedDx	11727419	F	55	0.00
82	PromMedDx	11727420	F	40	0.63
83	PromMedDx	11727423	F	48	0.00
84	PromMedDx	11727424	F	38	0.00
85	PromMedDx	11727427	F	50	1.23
86	PromMedDx	11727428	F	29	0.00
87	PromMedDx	11727430	F	52	0.00
88	PromMedDx	11727435	F	49	0.00
89	PromMedDx	11727436	F	55	0.00
90	PromMedDx	11727443	F	36	0.42
91	PromMedDx	11727444	F	45	0.90
92	PromMedDx	11727446	F	35	0.00
93	PromMedDx	11727453	F	39	0.00
94	PromMedDx	11727458	F	48	0.00
95	PromMedDx	11727471	F	41	0.00
96	PromMedDx	11727472	F	52	0.00
97	PromMedDx	11727475	F	22	0.40
98	PromMedDx	11700755	M	17	0.00
99	PromMedDx	11701162	M	48	0.00
100	PromMedDx	11701317	M	27	0.00
101	PromMedDx	11701375	M	42	0.19
102	PromMedDx	11701595	M	30	0.33
103	PromMedDx	11703286	M	25	1.31
104	PromMedDx	11703296	M	60	0.00
105	PromMedDx	11703297	M	58	0.00
106	PromMedDx	11703373	M	56	0.00
107	PromMedDx	11703384	M	50	0.00
108	PromMedDx	11703387	M	23	0.00
109	PromMedDx	11703401	M	49	0.35
110	PromMedDx	11703416	M	53	0.56
111	PromMedDx	11703417	M	54	0.00
112	PromMedDx	11703440	M	17	0.00
113	PromMedDx	11703495	M	44	0.00
114	PromMedDx	11703539	M	38	0.00
115	PromMedDx	11703581	M	31	0.26
116	PromMedDx	11703599	M	52	0.00
117	PromMedDx	11703604	M	29	0.00
118	PromMedDx	11703622	M	55	0.00
119	PromMedDx	11703657	M	61	0.19
120	PromMedDx	11703662	M	17	0.00
121	PromMedDx	11703664	M	17	0.07
122	PromMedDx	11703673	M	52	0.00
123	PromMedDx	11703689	M	19	0.12
124	PromMedDx	11703701	M	65	0.08
125	PromMedDx	11703705	M	21	0.07
126	PromMedDx	11703706	M	21	0.00
127	PromMedDx	11703730	M	37	0.00

No	Specimen	ID	Gender	Age	TropI (ng/ml)
128	PromMedDx	11703731	M	20	0.24
129	PromMedDx	11703732	M	17	0.35
130	PromMedDx	11703744	M	17	0.07
131	PromMedDx	11703752	M	20	0.26
132	PromMedDx	11703763	M	41	0.00
133	PromMedDx	11703791	M	60	0.00
134	PromMedDx	11703792	M	48	0.00
135	PromMedDx	11703803	M	71	0.00
136	PromMedDx	11703805	M	63	0.00
137	PromMedDx	11703807	M	58	0.00
138	PromMedDx	11703808	M	51	0.00
139	PromMedDx	11703811	M	18	0.03
140	PromMedDx	11703812	M	17	0.00
141	PromMedDx	11703818	M	47	0.63
142	PromMedDx	11727224	M	54	0.34
143	PromMedDx	11727225	M	51	0.00
144	PromMedDx	11727243	M	54	0.00
145	PromMedDx	11727248	M	44	0.00
146	PromMedDx	11727250	M	41	0.00
147	PromMedDx	11727254	M	25	0.00
148	PromMedDx	11727256	M	53	0.00
149	PromMedDx	11727262	M	21	0.00
150	PromMedDx	11727263	M	35	0.00
151	PromMedDx	11727264	M	55	0.00
152	PromMedDx	11727268	M	26	0.00
153	PromMedDx	11727270	M	25	0.00
154	PromMedDx	11727273	M	54	0.73
155	PromMedDx	11727274	M	37	0.00
156	PromMedDx	11727281	M	42	0.20
157	PromMedDx	11727282	M	27	0.00
158	PromMedDx	11727283	M	51	0.00
159	PromMedDx	11727286	M	46	0.00
160	PromMedDx	11727289	M	54	0.00
161	PromMedDx	11727292	M	39	0.37
162	PromMedDx	11727293	M	50	0.00
163	PromMedDx	11727294	M	24	0.23
164	PromMedDx	11727295	M	52	0.00
165	PromMedDx	11727297	M	28	0.00
166	PromMedDx	11727300	M	48	0.09
167	PromMedDx	11727304	M	25	0.65
168	PromMedDx	11727306	M	53	0.00
169	PromMedDx	11727309	M	28	0.37
170	PromMedDx	11727310	M	38	0.00

No	Specimen	ID	Gender	Age	TropI (ng/ml)
171	PromMedDx	11727314	M	45	0.39
172	PromMedDx	11727324	M	29	0.54
173	PromMedDx	11727325	M	32	0.18
174	PromMedDx	11727328	M	32	0.48
175	PromMedDx	11727335	M	50	0.22
176	PromMedDx	11727344	M	22	0.24
177	PromMedDx	11727347	M	27	0.65
178	PromMedDx	11727349	M	44	0.22
179	PromMedDx	11727355	M	35	0.00
180	PromMedDx	11727356	M	48	0.00
181	PromMedDx	11727357	M	31	0.00
182	PromMedDx	11727359	M	23	0.00
183	PromMedDx	11727363	M	32	0.06
184	PromMedDx	11727367	M	42	0.23
185	PromMedDx	11727368	M	52	0.00
186	PromMedDx	11727371	M	35	0.54
187	PromMedDx	11727375	M	54	1.08
188	PromMedDx	11727386	M	43	0.00
189	PromMedDx	11727393	M	37	0.00
190	PromMedDx	11727403	M	40	0.00
191	PromMedDx	11727410	M	45	0.18
192	PromMedDx	11727411	M	50	1.88

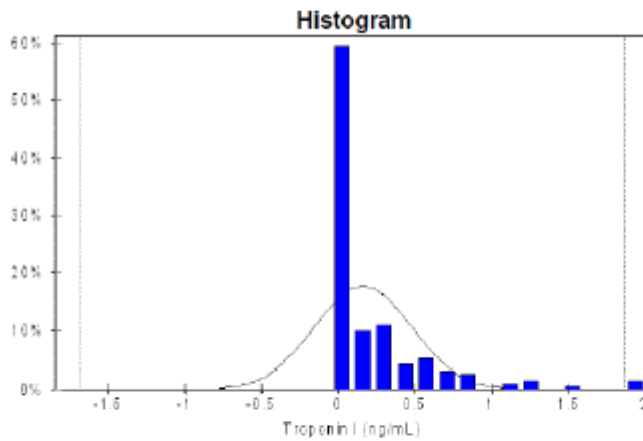
The data were processed using EP evaluator 8. The result is listed below:

Reference Interval Estimation: Combined

Central 95% Interval (N = 192)

	Lower		Upper		Confidence Ratio
	Value	90% CI	Value	90% CI	
Nonparametric (CLSI C28-A)	0.00	0.00 to 0.00	1.35	0.90 to 1.95	0.39
Alternatives:					
Parametric	-0.53	-0.61 to -0.45	0.96	0.88 to 1.04	0.10
Transformed Parametric	-	-	-	-	-

Confidence Limits for Nonparametric CLSI C-28A method computed from C28-A Table 8.



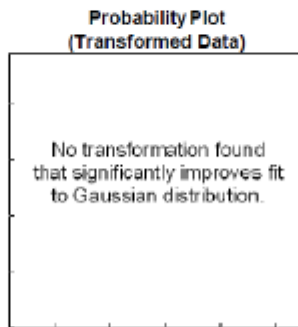
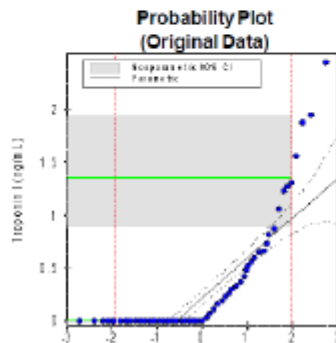
Selection Criteria:

Bounds: None
Filter: None

Statistics:

Mean: 0.215 ng/mL
SD: 0.380
Median: 0.000
Range: 0.00 to 2.45
N: 192 of 192
Distinct values: 59
Zeros: 98
Central 95% Index: 4.8 to 188.2

Analyst: G
Expt. Date: 14 Jan 2013



Normalizing Transformation

Exponent: --
Constant: --

Conclusion:

SMART Cardiac Troponin I assay was used in the reference interval study according to CLSI C28-A3 protocol with serum specimens from apparently healthy adults in the age range of 16-71. The reference range interval was calculated using non-parametric statistics representing the central 95% of the population. Results indicated a reference range of 0.00-1.35 ng/ml. The cut off for POC analysis is set to **0.00-1.50 ng/ml**

Each laboratory, however, is recommended to establish a range of normal values for the population in their region.

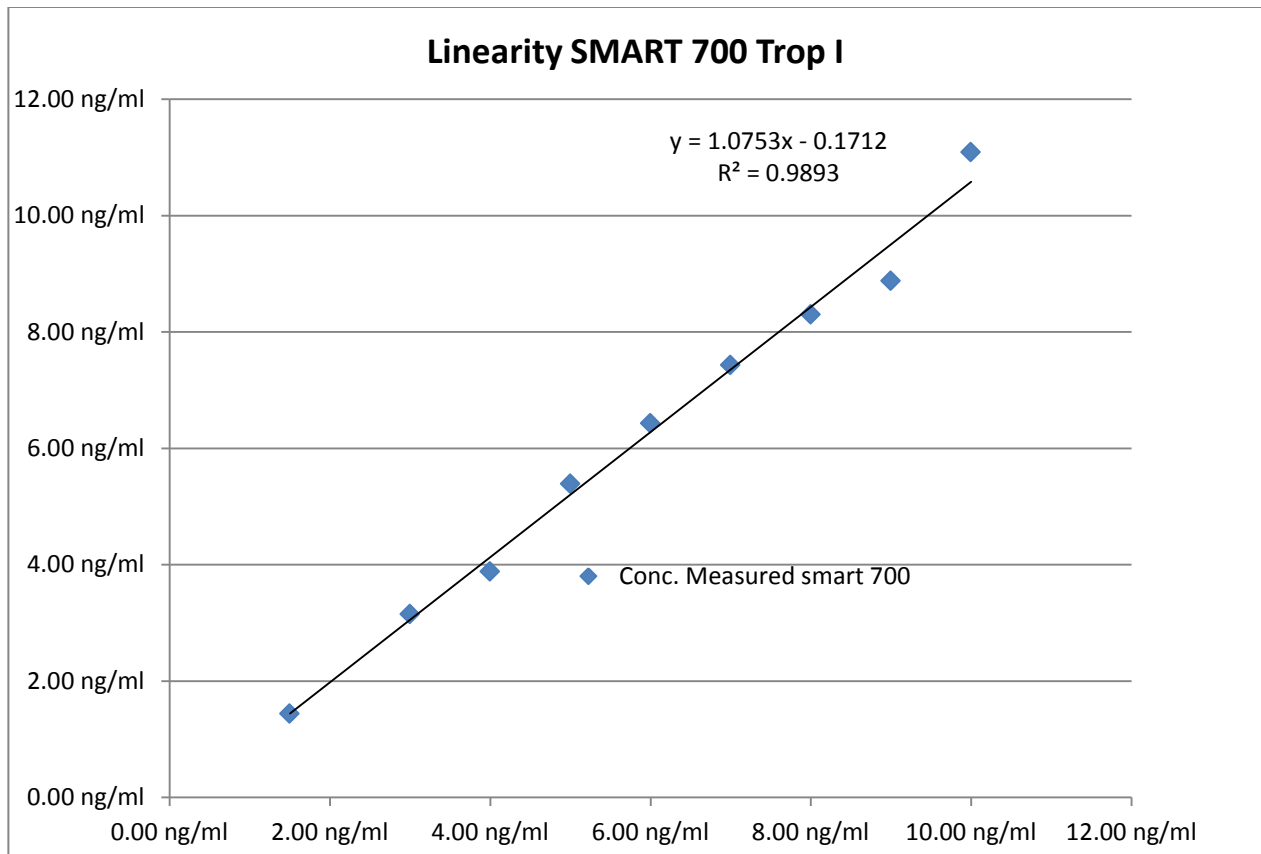
1.2 Performance Characteristics

1.2.1 within run precision using Tropl control Low and high

No	2.57 ng/ml	5.77 ng/ml
	Control low	Control high
1	2.50 ng/ml	6.04 ng/ml
2	2.42 ng/ml	6.17 ng/ml
3	2.26 ng/ml	6.60 ng/ml
4	2.70 ng/ml	6.36 ng/ml
5	2.74 ng/ml	4.99 ng/ml
6	2.55 ng/ml	5.88 ng/ml
7	2.66 ng/ml	6.22 ng/ml
8	2.55 ng/ml	6.50 ng/ml
9	2.56 ng/ml	6.51 ng/ml
10	2.53 ng/ml	6.18 ng/ml
11	2.55 ng/ml	5.90 ng/ml
12	2.68 ng/ml	6.19 ng/ml
13	2.69 ng/ml	6.22 ng/ml
14	2.71 ng/ml	6.26 ng/ml
15	2.61 ng/ml	6.49 ng/ml
16	2.16 ng/ml	6.10 ng/ml
17	2.21 ng/ml	6.18 ng/ml
18	2.51 ng/ml	6.50 ng/ml
19	2.52 ng/ml	6.50 ng/ml
20	2.55 ng/ml	6.21 ng/ml
mean	2.53 ng/ml	6.20 ng/ml
stabwn	0.163	0.351
cv	6.44%	5.65%

1.2.2 Linearity measured with diluted serum calibrators:

Conc. Diluted Standard	Conc. Measured smart 700
1,50 ng/ml	1,44 ng/ml
3,00 ng/ml	3,15 ng/ml
4,00 ng/ml	3,88 ng/ml
5,00 ng/ml	5,39 ng/ml
6,00 ng/ml	6,43 ng/ml
7,00 ng/ml	7,43 ng/ml
8,00 ng/ml	8,30 ng/ml
9,00 ng/ml	8,88 ng/ml
10,00 ng/ml	11,09 ng/ml



The linearity results into $y = 1.0753x - 0.1712$ $y = \text{Theoretical Trop I value}$ $x = \text{SMART700 Trop I value}$
 $R^2 = 0.9893$

References

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3. Mair J, Wagner I, Jakob G, Lechleitner P, Dienstl F, Puschendorf B, Michel G: Different time courses of cardiac contractile proteins after acute myocardial infarction. *Clin Chim Acta* 1994;231:47-60
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5. Katus HA, Remppis A, Neumann FJ, Scheffold T, Diederich KW, Vinar G, Noe A, Matern G, Kuebler W: Diagnostic efficiency of troponin T measurements in acute myocardial infarction. *Circulation* 1991;83:902-912
6. Wang K, Asinger RW, Marriott HJ. ST-segment elevation in conditions other than acute myocardial infarction. *N Engl J Med* 2003;349:2128-2135