Performance of Troponin assays in Wales

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Study Design

- This study was a repeat of previous work conducted to establish the performance of Troponin assays in Wales. The aim of the study was to determine the intralaboratory variation (both within and between batch) at a range of Troponin concentration for all laboratories in Wales and to establish the coefficient of variation at or near the limit of detection of the assay.

Thomas MA, **Singh GK**, **Williams EJ**, **McDowell IF**, **Tovey JA**, **Wayte AM**;
A review of troponin assay performance in Wales: can the same (method-dependent) decision limits be used in different sites?
Ann Clin Biochem. 2005 Sep;42(Pt 5):351-6.

Material

- A base pool of human serum from a healthy donor was spiked with ternary Troponin complex (ITC) to an approximate concentration of 30 ng/L TnI as measured on the Abbott hs method. Doubling dilutions using the base serum were prepared to give final concentrations close to the cut off points of all the methods, sample 1 was the endogenous base serum. The samples were aliquotted and stored at -70°C until dispatch. Ten sets of 4 pools were dispatched to all laboratories and stored at -20°C.

Protocol

- The protocol consisted of two replicates per pool per run, and two runs per day for 5 days (10 runs). The laboratories were asked to analyse the samples as if they were patient samples, therefore calibration frequency and reagent lot numbers was laboratory dependent.

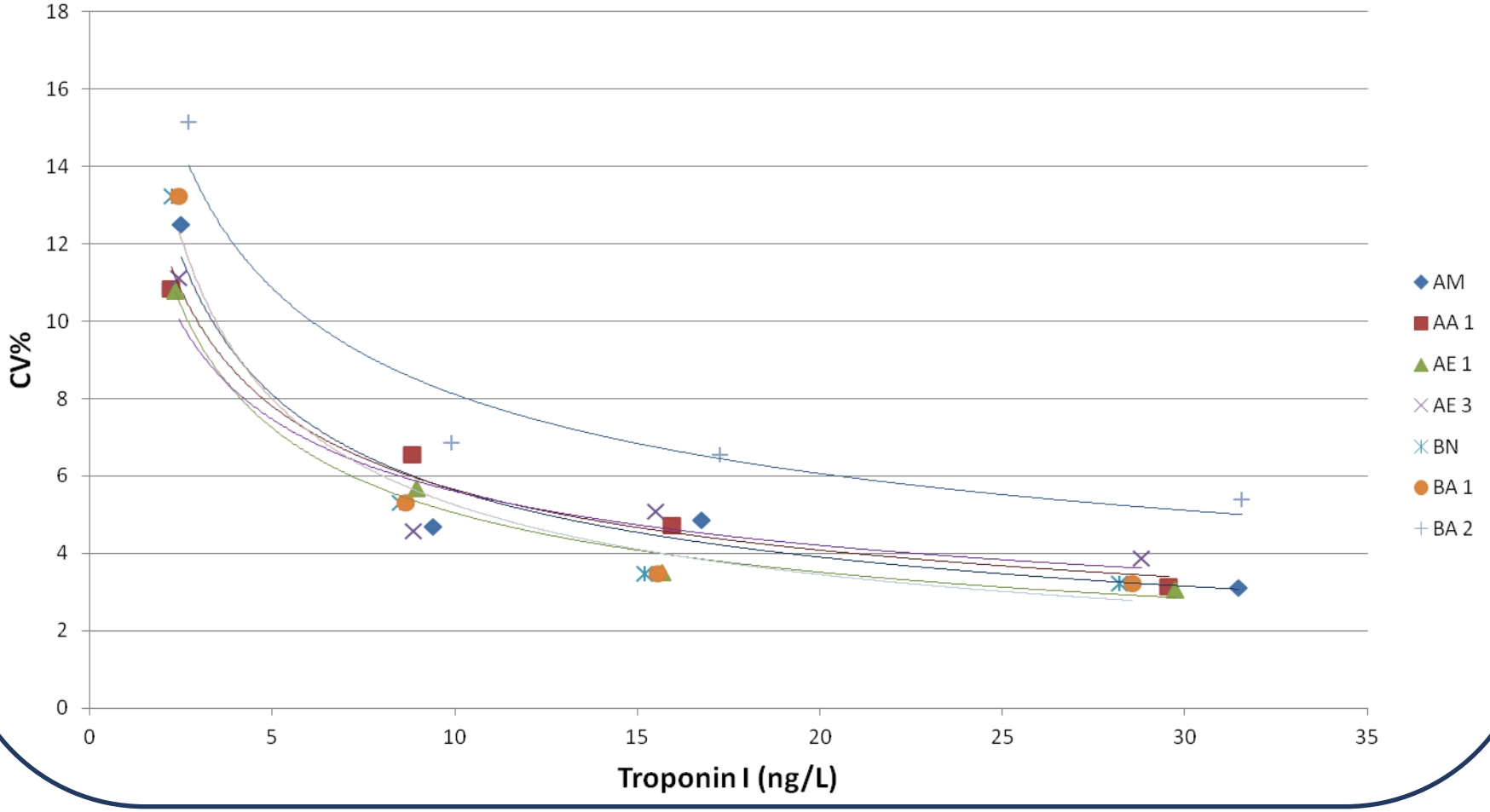
- Each laboratory carried out 80 assays.

Lab	labelled white		labelled blue		labelled pink		labelled yellow			
	Sample1		Sample2		Sample3		Sample4		Reagent batch no	Calib. lot no
	Result 1	Result 2	Result 1	Result 2	Result 1	Result 2	Result 1	Result 2		
Event 1 (day 1 a.m)										
Event 2 (day 1 p.m.)										
Event 3 (day 2 a.m.)										
Event 4 (day 2 p.m.)										
Event 5 (day 3 a.m.)										
Event 6 (day 3 p.m.)										
Event 7 (day 4 a.m)										
Event 8 (day 4 p.m.)										
Event 9 (day 5 a.m)										
Event 10 (day 5 p.m.)										
Sum d^2	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
SD $_{diff}$	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
Within run CV (%)	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
Between Batch CV Result 1(%)	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
Between Batch CV Result 2(%)	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
Overall CV (%)	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
Mean	#DIV/0!		#DIV/0!		#DIV/0!		#DIV/0!			
DATE SAMPLES RECEIVED:	10-Oct									
DATE OF ANALYSIS DAY 1:	13-Oct				RETURN BY DATE IS: 10th November					

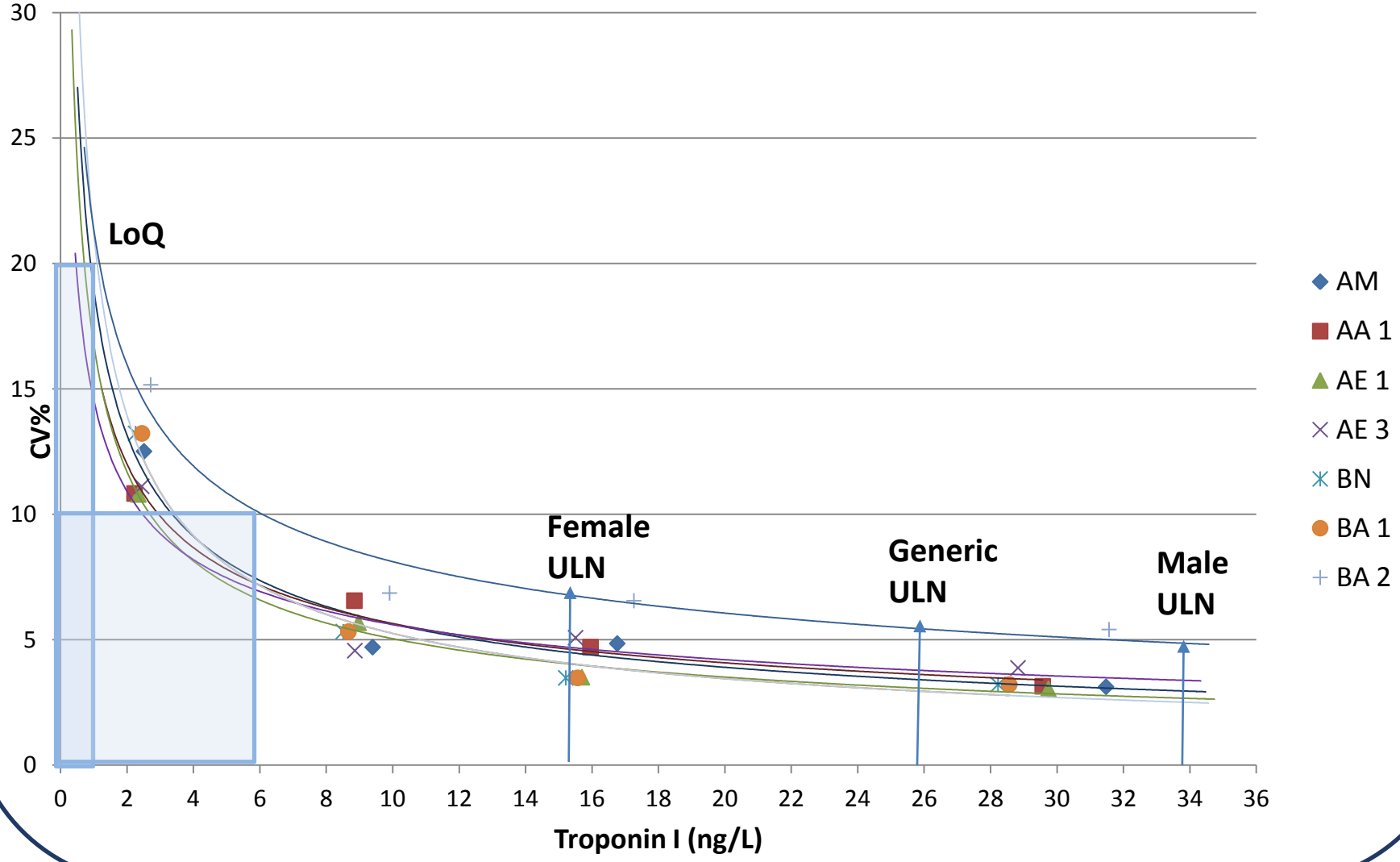
Tn concentration (ng/L)

	Sample 1	Sample 2	Sample 3	Sample 4
Roche cTnT-hs	3.80	13.95	22.62	38.20
Abbott TnI	2.35	8.85	15.72	29.29

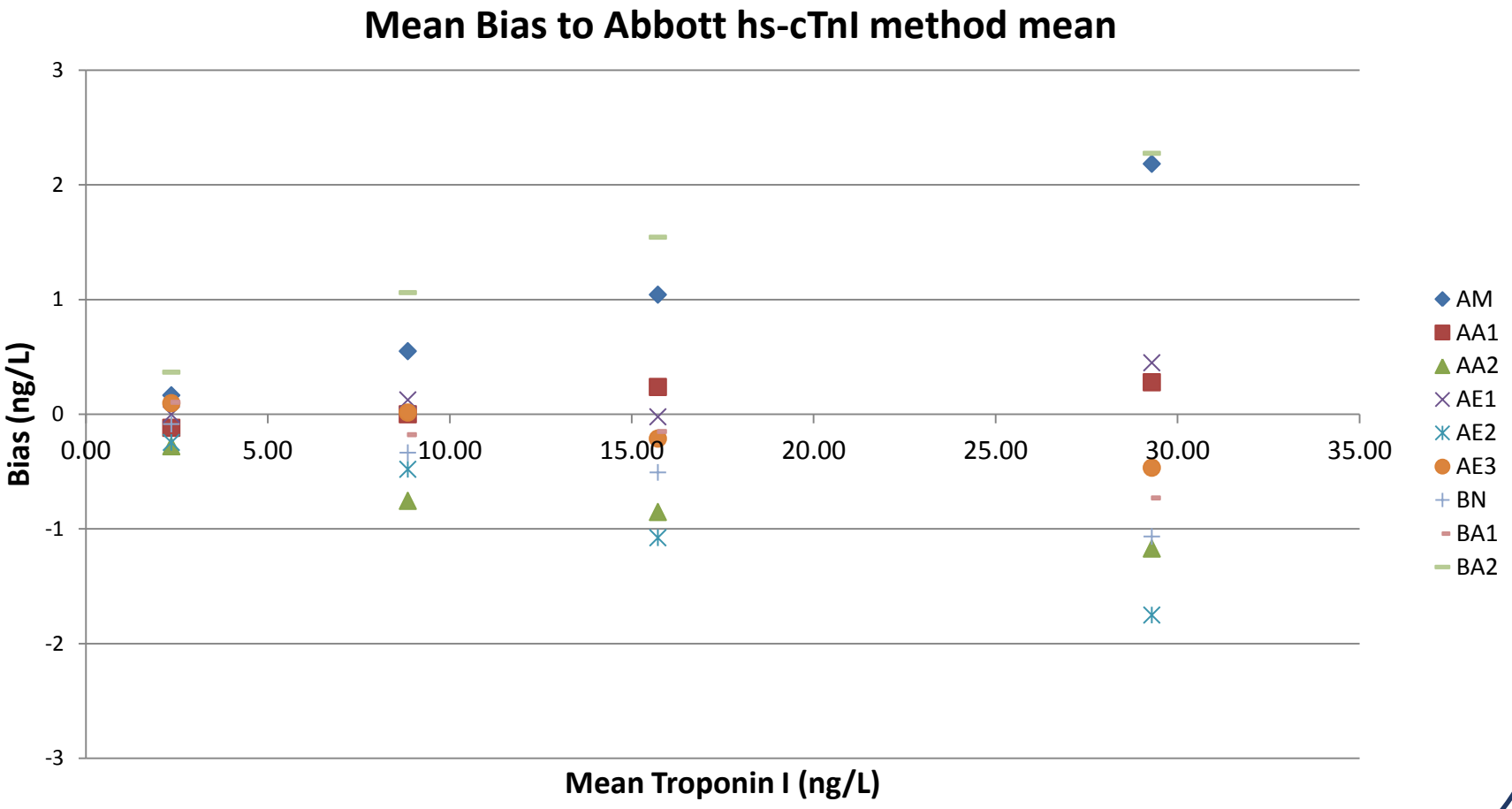
Intralaboratory variation Abbott hs - cTnI



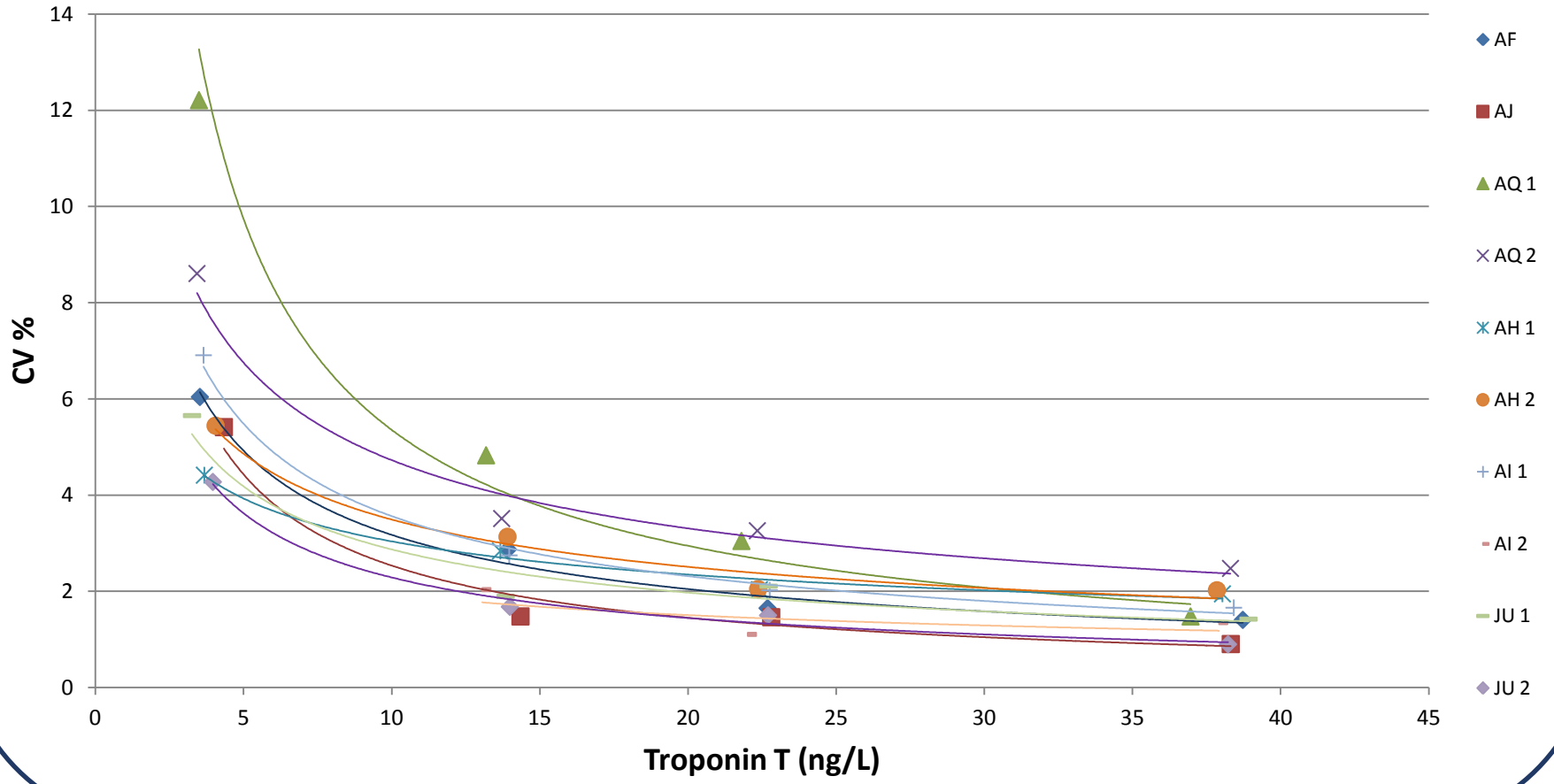
Intralaboratory variation Abbott hs-cTnI



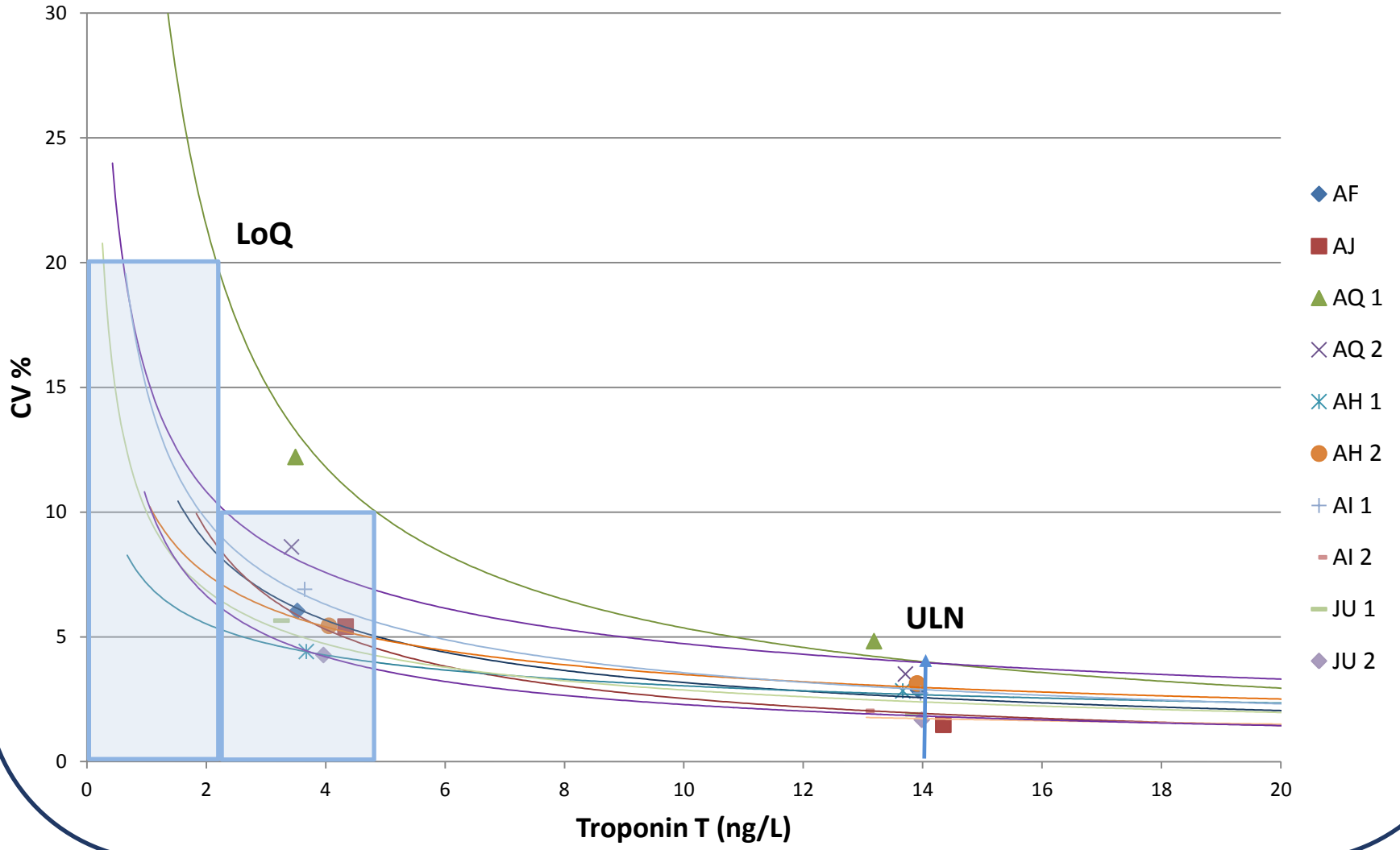
Laboratory bias to Abbott hs-cTnI method mean



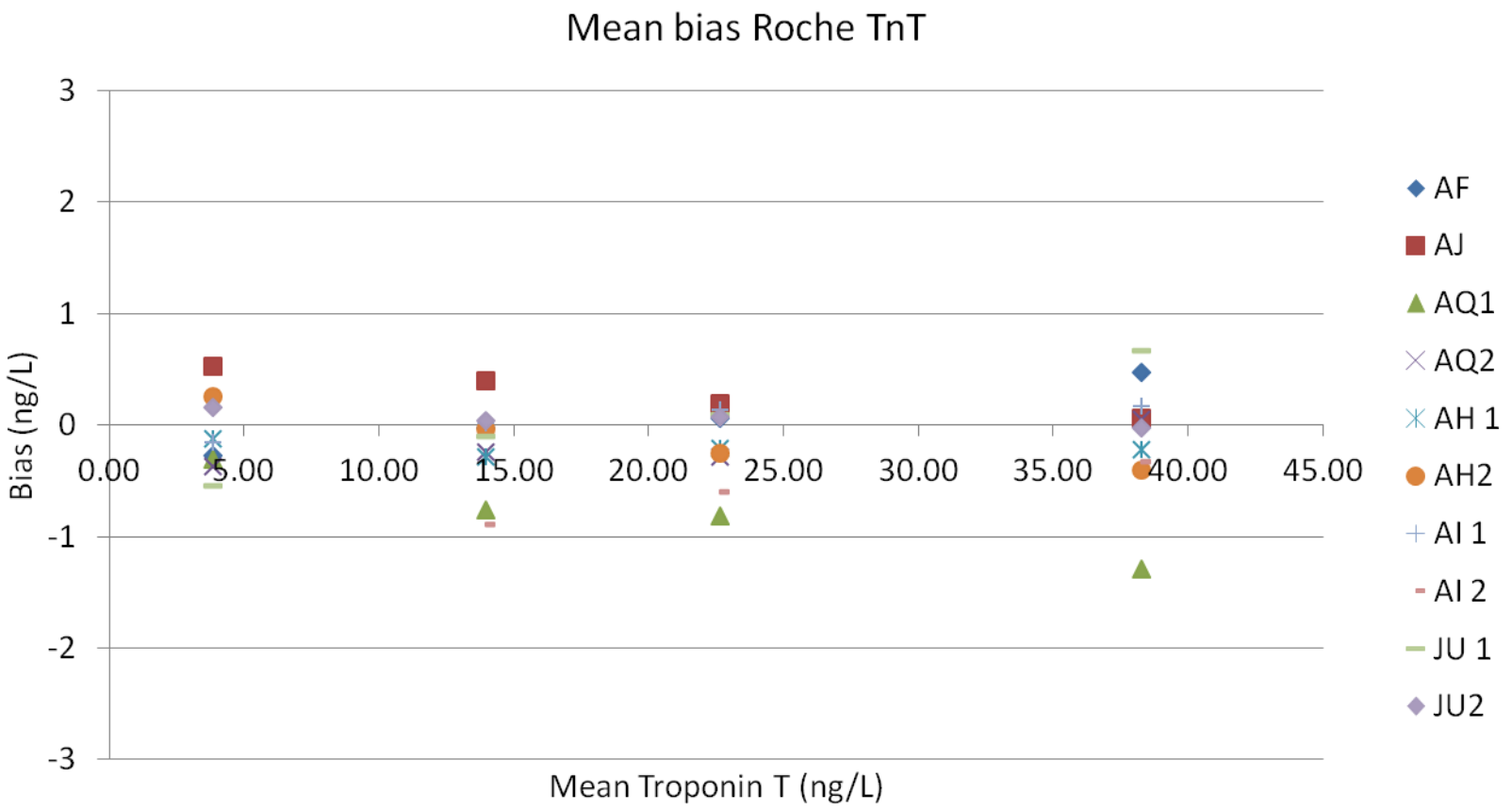
Intralaboratory variation – Roche TnT



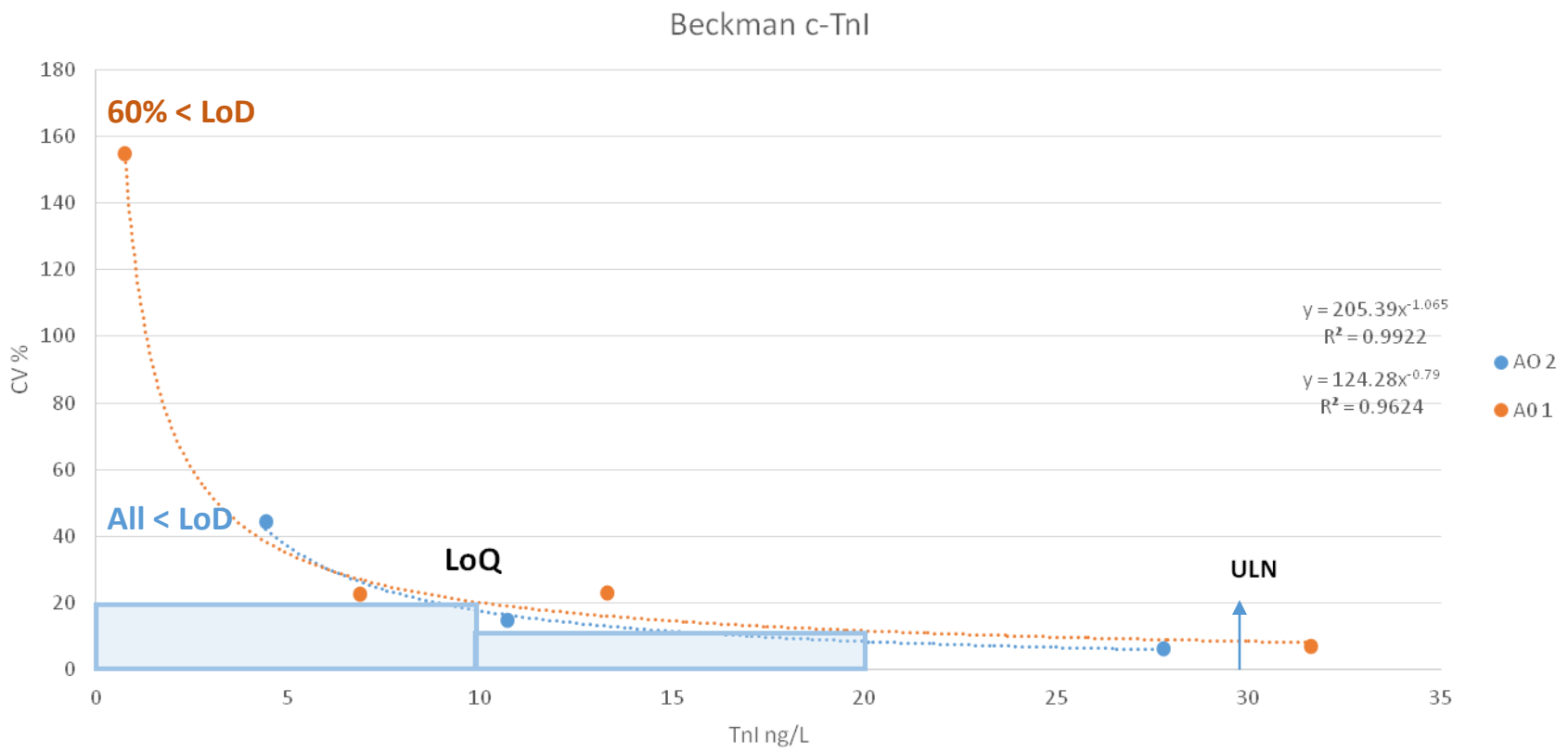
Intralaboratory variation – Roche TnT



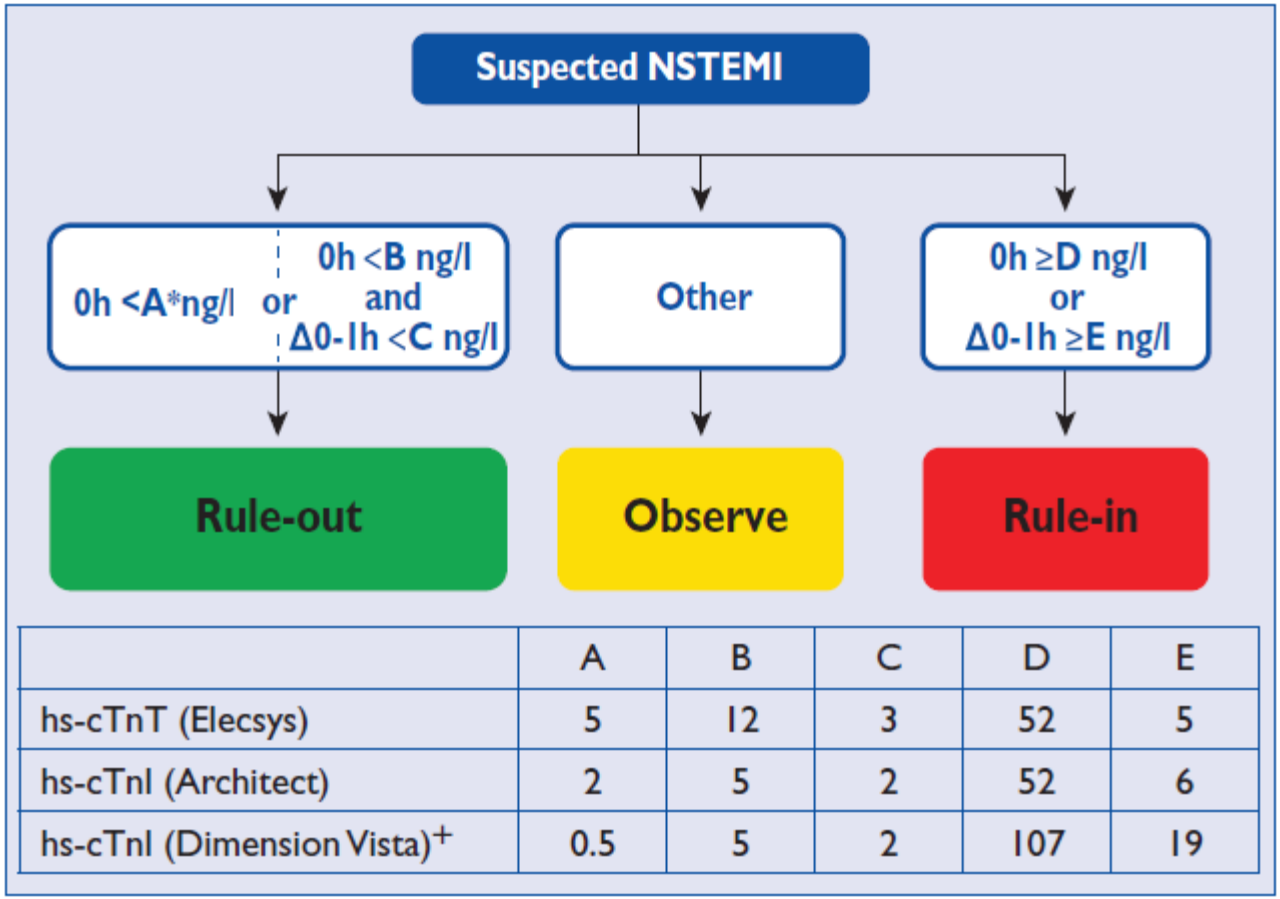
Laboratory bias Roche hs-cTnT



Intralaboratory variation – Beckman DXI



ESC guidelines 0/1 hr



	A	B	C	D	E
hs-cTnT (Elecsys)	5	12	3	52	5
hs-cTnI (Architect)	2	5	2	52	6
hs-cTnI (Dimension Vista)+	0.5	5	2	107	19

European Heart Journal (2016) **37**, 267–315
doi:10.1093/eurheartj/ehv320

Performance at ECS 0h/1h rule - out Roche hs-cTnT

	CV% at 5 ng/L A	CV% at 12 ng/L B	CV% at 14 ng/L ULN	Tn at 10%CV ng/L
AF	4.9	2.8	2.6	1.6
AJ	4.4	2.2	1.9	1.8
AQ1	9.7	4.6	4.0	4.8
AQ2	6.8	4.3	4.0	2.3
AH1	3.9	2.8	2.7	0.4
AH2	4.9	3.2	3.0	1.1
AI1	4.9	4.0	3.9	0.2
AI2	2.6	1.8	1.7	0.1
JU1	4.2	2.6	2.4	1.0
JU2	3.6	2.0	1.8	1.1

Performance at ECS 0h/1h rule - out Abbott hs-cTnI

	CV% at 2 ng/L A	CV% at 5 ng/L B	CV% at 26 ng/L ULN	Tn at 10%CV ng/L
AM	13.1	8.1	3.4	3.4
AA1	12.0	7.8	3.6	3.0
AE1	11.7	7.2	3.1	2.7
AE3	10.9	7.5	3.8	2.5
BN	13.3	7.8	2.9	3.2
BA1	13.9	8.0	2.9	3.5
BA2	16.0	10.8	5.4	6.1

Performance at ULN - Beckman Dxi - cTnT

	CV% at 30 ng/L	Tn at 10%CV
AO1	9.5	24.3
AO2	6.4	17.1

New hsTnI assay – in development		
LoD	2.5 ng/L	
Tn at 10% CV	8 ng/L	
99th centile	32 ng/L	8% Total CV
% normal	>80%	