

Precision

Sample ID	Mean	SD	95% CI	CV
Blank-1	2.98	3.38	2.60 to 8.84	113.7%
Blank-2	3.79	3.18	2.47 to 5.82	83.8%
Blank-3	2.59	4.72	3.57 to 18.09	182.1%
Blank-4	3.58	3.11	2.33 to 13.49	87.1%
Blank-5	3.04	3.45	2.61 to 13.67	113.4%
Low-1	25.01	3.34	2.58 to 7.63	13.3%
Low-2	14.23	2.31	1.78 to 5.24	16.2%
Low-3	13.88	2.71	2.08 to 7.36	19.6%
Low-4	21.62	3.69	2.79 to 14.62	17.1%
Low-5	25.12	3.90	3.00 to 9.91	15.5%

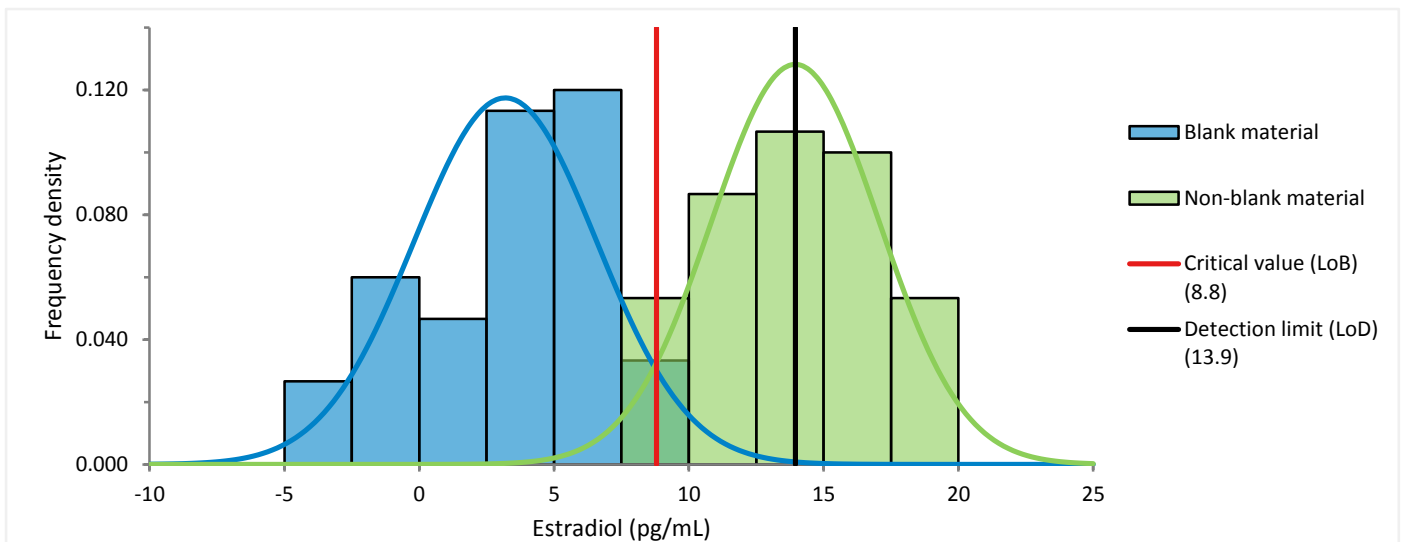
Detection Capability

Detection Decision

	N	Mean	SD	Alpha	Critical value (LoB)
Blank material	60	3.20	3.40	5%	8.8

Detection Limit

	N	Pooled SD	Beta	Detection limit (LoD)
Non-blank material	60	3.11	5%	13.9



Precision

Sample ID	Mean	SD	95% CI	CV
Blank-1	1.87	2.65	1.90 to 12.96	141.9%
Blank-2	6.73	2.42	1.88 to 4.03	36.0%
Blank-3	2.33	2.25	1.64 to 10.63	96.3%
Blank-4	5.28	2.38	1.84 to 5.96	45.2%
Blank-5	3.28	2.23	1.72 to 5.12	67.9%
Low-1	23.66	2.42	1.74 to 11.83	10.2%
Low-2	17.88	2.96	2.27 to 8.22	16.6%
Low-3	12.18	3.39	2.55 to 10.84	27.8%
Low-4	18.36	2.68	2.02 to 11.30	14.6%
Low-5	30.56	2.26	1.74 to 6.02	7.4%

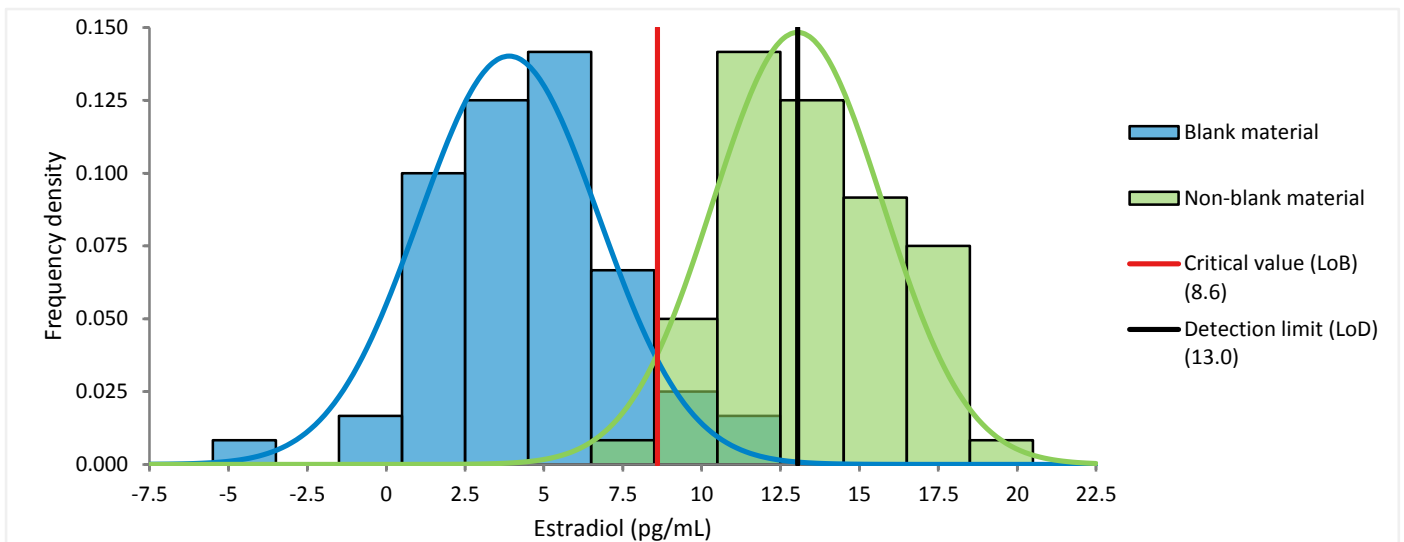
Detection Capability

Detection Decision

	N	Mean	SD	Alpha	Critical value (LoB)
Blank material	60	3.90	2.85	5%	8.6

Detection Limit

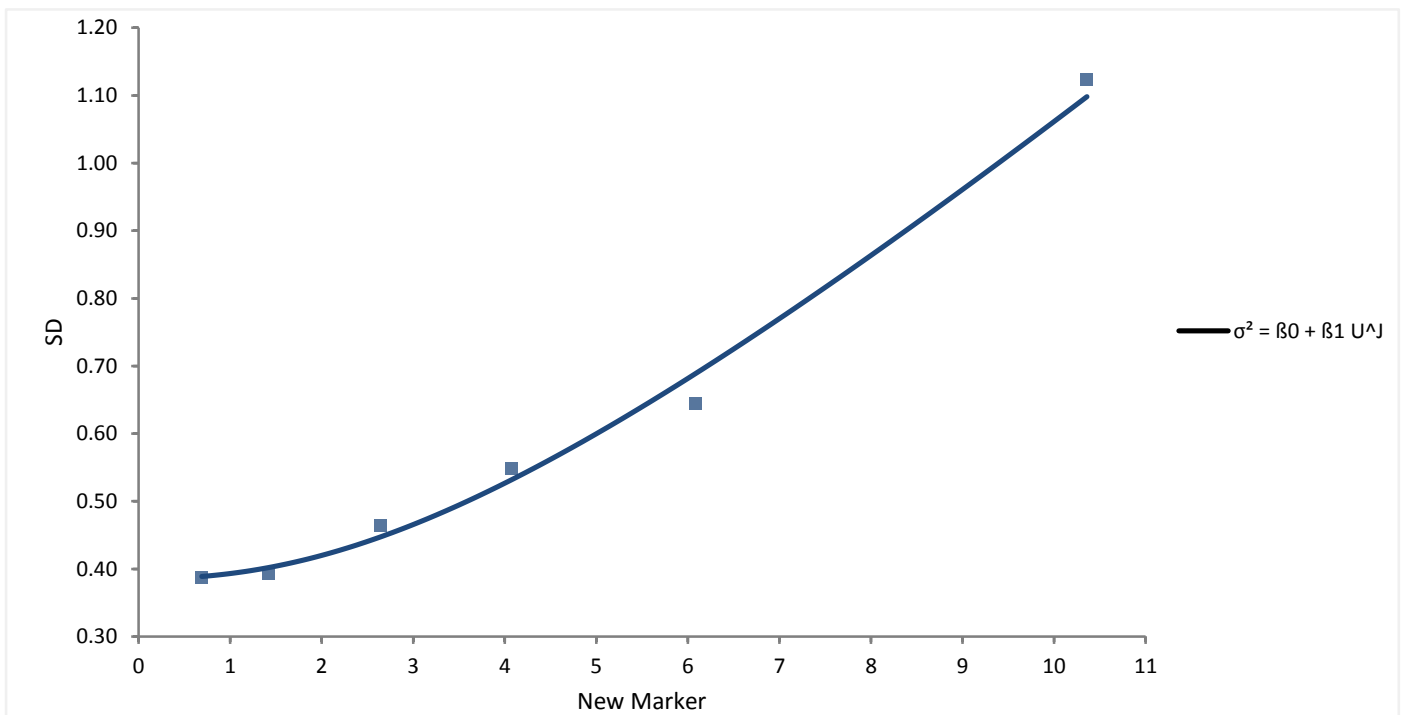
	N	Pooled SD	Beta	Detection limit (LoD)
Non-blank material	60	2.69	5%	13.0



Precision

X	Mean	SD	95% CI	CV
A	0.690	0.387	0.335 to 0.458	56.1%
B	1.420	0.392	0.339 to 0.464	27.6%
C	2.650	0.464	0.402 to 0.550	17.5%
D	4.080	0.548	0.474 to 0.649	13.4%
E	6.080	0.645	0.558 to 0.764	10.6%
F	10.360	1.123	0.972 to 1.330	10.8%

Profile



Model | 3-parameter alternative power variance function  
 Equation |  $\sigma^2 = \beta_0 + \beta_1 U^J$

Parameter	
$\beta_0$	0.1485
$\beta_1$	0.006009
J	2.212

-LogLikelihood | 1.1708

## MSA: New Marker

CLSI EP17-A2 - Appendix B (generated data to achieve given Mean/SD for each pool)

Last updated 23 June 2015 at 15:05 by Simon Huntington

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### Detection Capability

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Detection Decision

			Critical value (LoB)
Known value	Alpha	5%	0.51

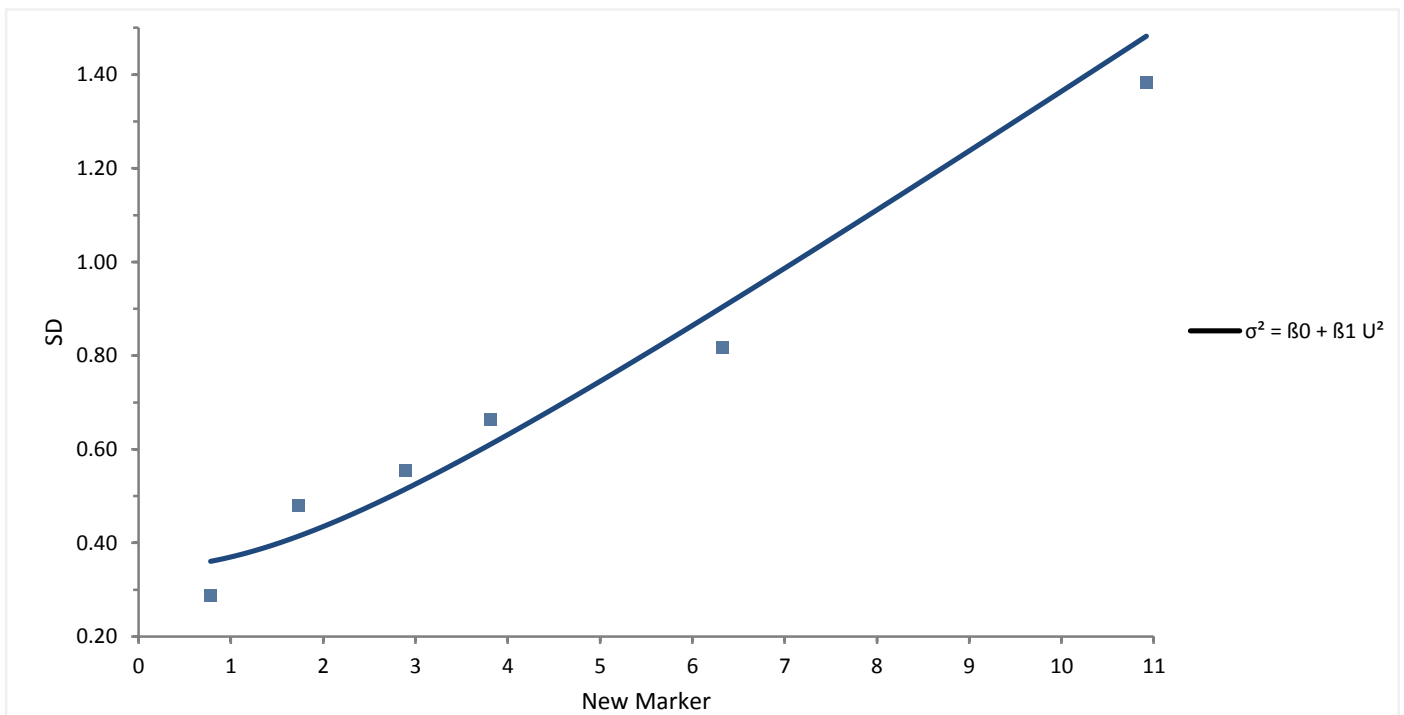
Detection Limit

				Detection limit (LoD)
Profile at LoD	Profile SD	Beta	5%	1.16

Precision

X	Mean	SD	95% CI	CV
A	0.780	0.288	0.249 to 0.341	36.9%
B	1.730	0.480	0.415 to 0.569	27.7%
C	2.890	0.554	0.479 to 0.656	19.2%
D	3.820	0.663	0.574 to 0.785	17.4%
E	6.330	0.816	0.706 to 0.967	12.9%
F	10.920	1.382	1.196 to 1.637	12.7%

Profile



Model | Mixed constant / proportional variance function  
 Equation |  $\sigma^2 = \beta_0 + \beta_1 U^2$

Parameter	
$\beta_0$	0.1194
$\beta_1$	0.01742

-LogLikelihood | 15.001

## MSA: New Marker

CLSI EP17-A2 - Appendix B (generated data to achieve given Mean/SD for each pool)

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### Detection Capability

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Detection Decision

	Alpha	Critical value (LoB)
Known value	5%	0.51

Detection Limit

	Profile SD	Beta	Detection limit (LoD)
Profile at LoD	0.376	5%	1.13

# MSA: Troponin I

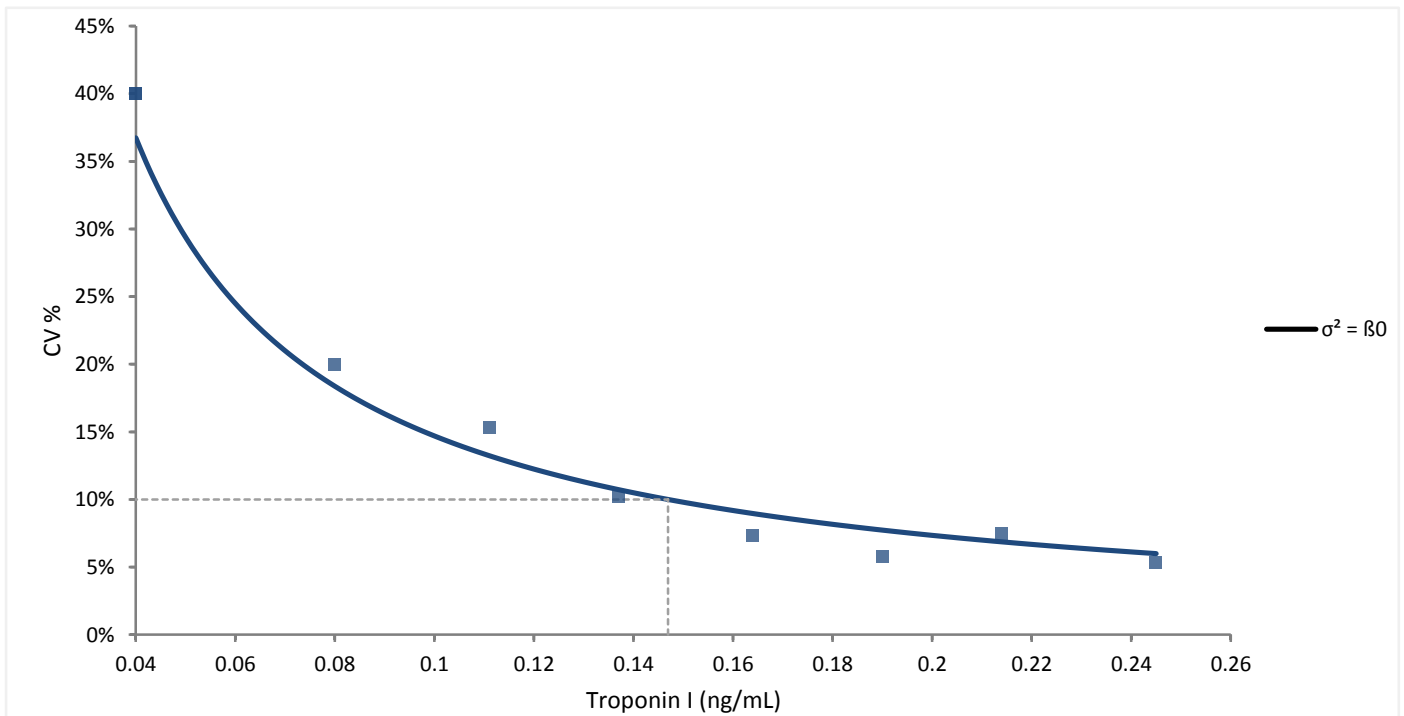
CLSI EP17-A2 - Appendix D (generated data to achieve given Mean/SD for each pool)

Last updated 23 June 2015 at 15:05 by Simon Huntington

## Precision

ID	Mean	SD	95% CI	CV
Pool 1	0.040	0.016	0.014 to 0.019	40.0%
Pool 2	0.040	0.016	0.014 to 0.019	40.0%
Pool 3	0.080	0.016	0.014 to 0.019	20.0%
Pool 4	0.111	0.017	0.015 to 0.020	15.3%
Pool 5	0.137	0.014	0.012 to 0.017	10.2%
Pool 6	0.164	0.012	0.010 to 0.014	7.3%
Pool 7	0.190	0.011	0.010 to 0.013	5.8%
Pool 8	0.214	0.016	0.014 to 0.019	7.5%
Pool 9	0.245	0.013	0.011 to 0.015	5.3%

## Profile



Model | Constant variance function  
Equation |  $\sigma^2 = \beta_0$

Parameter	
$\beta_0$	2.159 E-04

-LogLikelihood | 27.818

## Inverse Prediction

CV	X
10.0%	0.15

# MSA: Troponin I

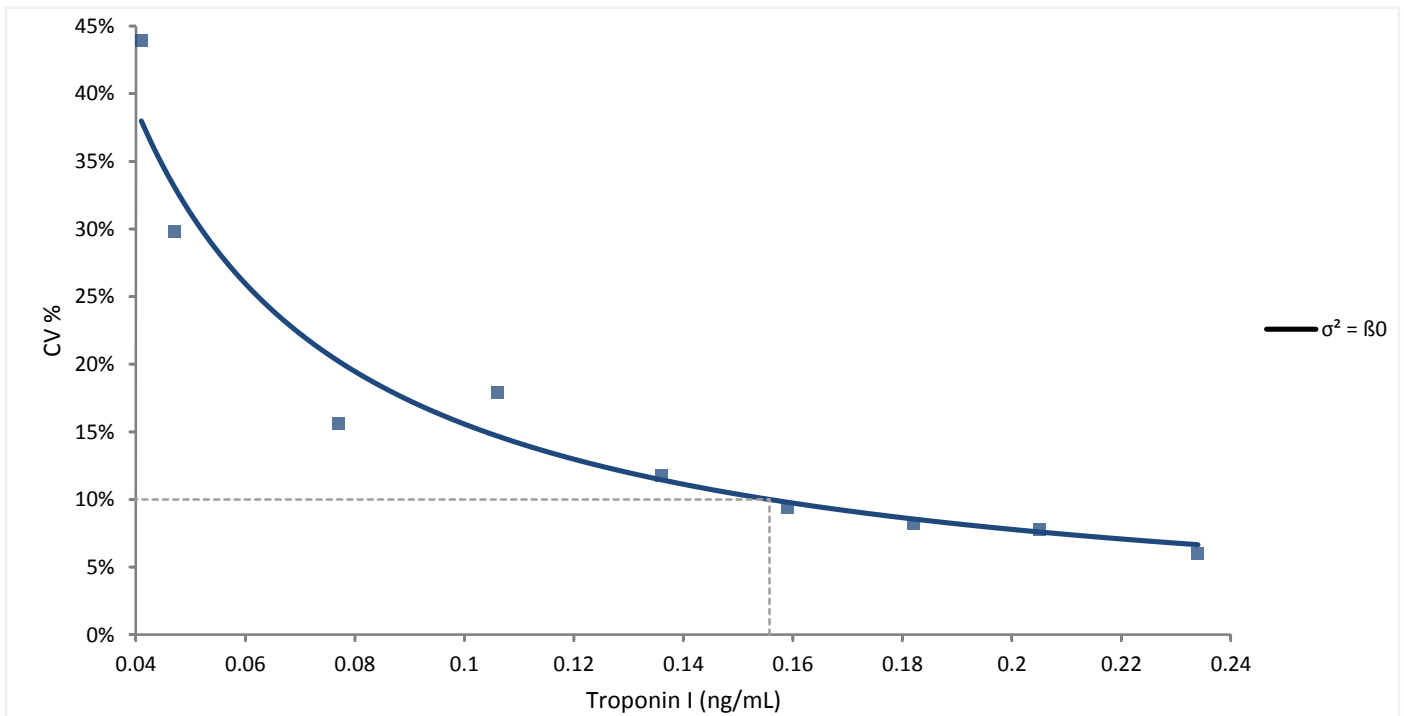
CLSI EP17-A2 - Appendix D (generated data to achieve given Mean/SD for each pool)

Last updated 23 June 2015 at 15:05 by Simon Huntington

## Precision

ID	Mean	SD	95% CI	CV
Pool 1	0.041	0.018	0.016 to 0.021	43.9%
Pool 2	0.047	0.014	0.012 to 0.017	29.8%
Pool 3	0.077	0.012	0.010 to 0.014	15.6%
Pool 4	0.106	0.019	0.016 to 0.023	17.9%
Pool 5	0.136	0.016	0.014 to 0.019	11.8%
Pool 6	0.159	0.015	0.013 to 0.018	9.4%
Pool 7	0.182	0.015	0.013 to 0.018	8.2%
Pool 8	0.205	0.016	0.014 to 0.019	7.8%
Pool 9	0.234	0.014	0.012 to 0.017	6.0%

## Profile



Model | Constant variance function  
Equation |  $\sigma^2 = \beta_0$

Parameter	
$\beta_0$	2.425 E-04

-LogLikelihood | 23.926

## Inverse Prediction

CV	X
10.0%	0.16