

Biolab SRL

COAGULATION END OF CYCLE REPORT

CYCLE 11

Authorised by: Stephen Doherty, RIQAS Manager

Issue No: 1

Issue Date: 03/02/2020

Randox Laboratories Limited
55 Diamond Road
CRUMLIN BT29 4QY
Tel: +44 (0)28 9445 4399
Fax: +44 (0)28 9445 4398
Email: mail@riqas.com

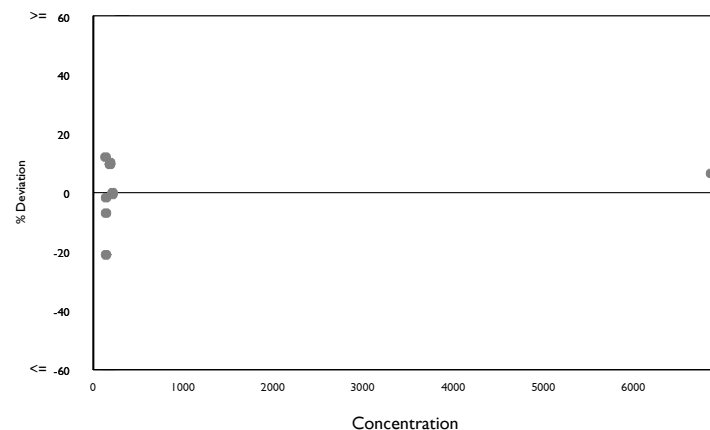
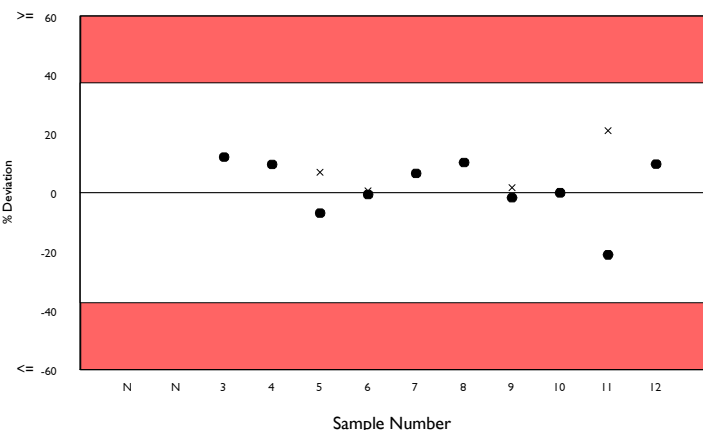
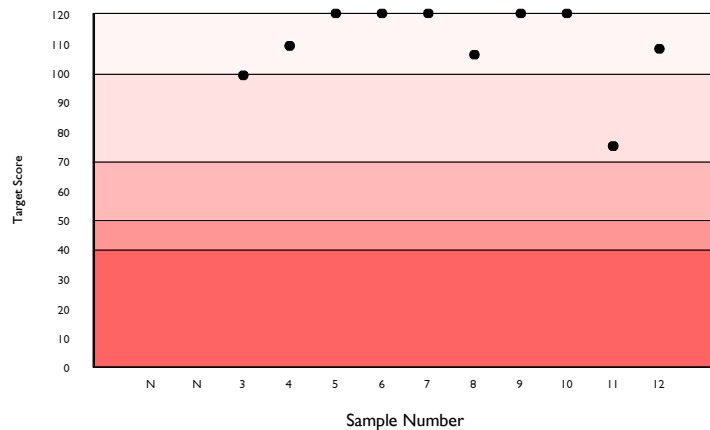
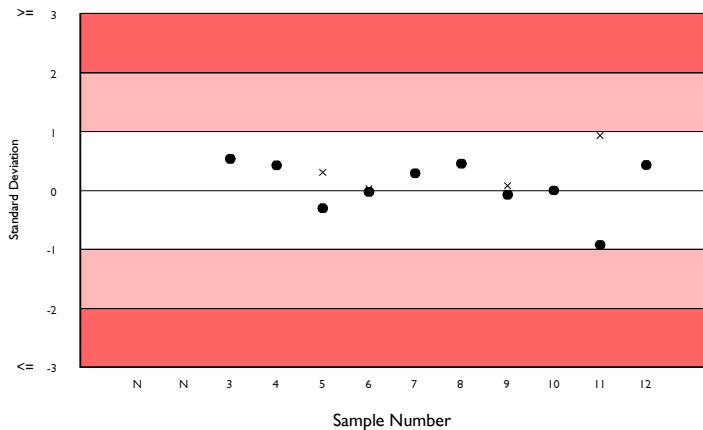
D-Dimer (Pilot), ng/ml FEU (2:1)

Method: Biomerieux VIDAS Exclusion II
Instrument: Biomerieux Vidas/miniVidas/Vidas 3
Reagent: bioMerieux

RIQAS TDPA: 37.3% **Biological Variation:** 28.04%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	ng/ml FEU (2:1)	47	212.326	8.8	3.40	48.15			
2	No Result	ng/ml FEU (2:1)	64	184.660	6.9	2.00	41.87			
3	154.210	ng/ml FEU (2:1)	65	137.587	7.5	1.61	31.20	0.53	99	12.08
4	204.150	ng/ml FEU (2:1)	62	186.261	6.0	1.78	42.24	0.42	109	9.60
5	132.590	ng/ml FEU (2:1)	66	142.433	6.9	1.50	32.30	-0.30	120	-6.91
6	210.870	ng/ml FEU (2:1)	65	212.189	6.0	1.97	48.12	-0.03	120	-0.62
7	7302.270	ng/ml FEU (2:1)	59	6853.118	5.6	62.93	1554.07	0.29	120	6.55
8	207.350	ng/ml FEU (2:1)	63	188.084	5.5	1.63	42.65	0.45	106	10.24
9	139.500	ng/ml FEU (2:1)	50	141.918	6.4	1.61	32.18	-0.08	120	-1.70
10	215.860	ng/ml FEU (2:1)	66	215.919	6.0	2.01	48.96	-0.00	120	-0.03
11	113.670	ng/ml FEU (2:1)	62	143.982	6.4	1.47	32.65	-0.93	75	-21.05
12	205.970	ng/ml FEU (2:1)	65	187.722	5.8	1.70	42.57	0.43	108	9.72

	Cycle 10	Cycle 11
Cycle Average SDI	0.91	0.08
Cycle Average TS	0	110
Cycle Average %DEV	7.11	1.79
Cycle Average Absolute SDI	0.98	0.35
Cycle Average Absolute %DEV	7.41	7.85



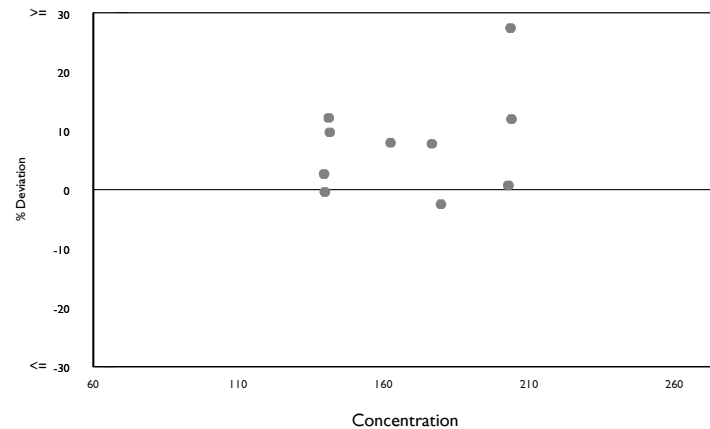
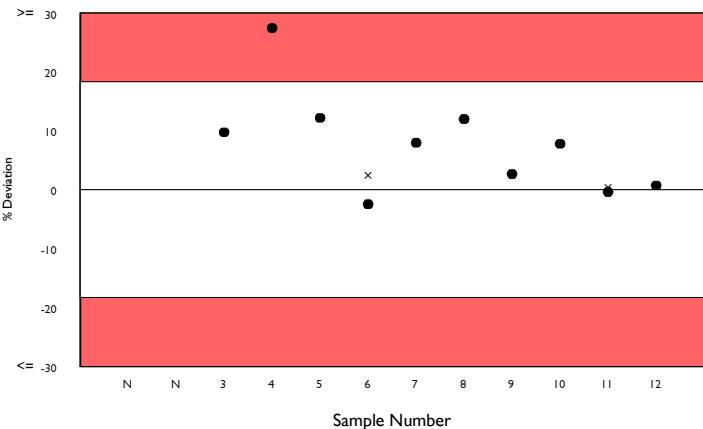
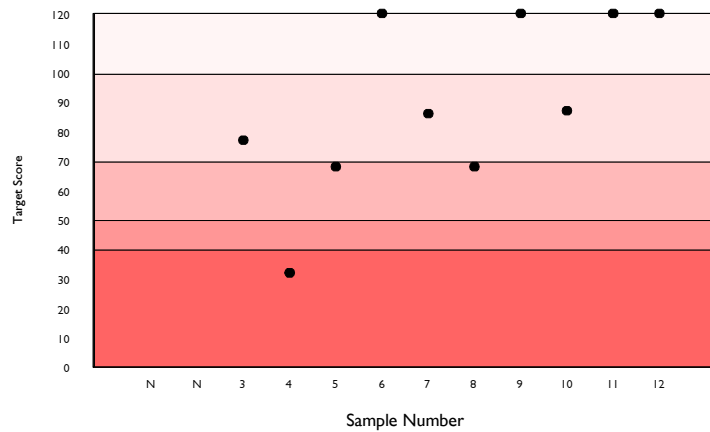
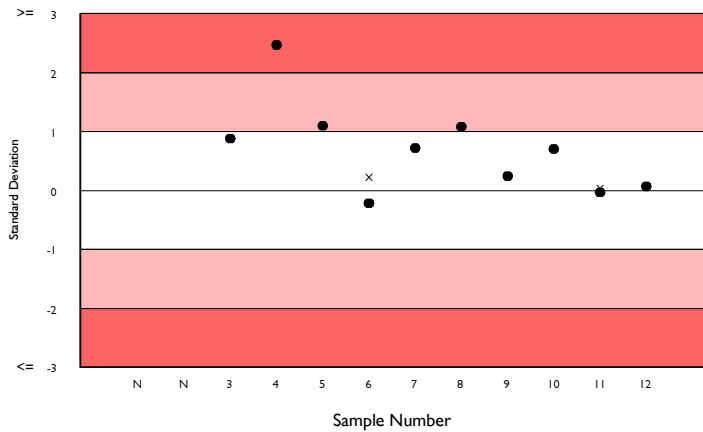
Fibrinogen, mg/dl

Method: HemosIL QFA (bovine thrombin)
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 18.3% **Biological Variation:** 13.6%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	mg/dl	53	178.853	5.3	1.63	19.89			
2	No Result	mg/dl	102	204.569	6.9	1.75	22.75			
3	155.000	mg/dl	117	141.232	5.5	0.89	15.71	0.88	77	9.75
4	259.000	mg/dl	125	203.256	6.4	1.45	22.61	2.47	32	27.43
5	158.000	mg/dl	127	140.852	6.0	0.94	15.67	1.09	68	12.17
6	175.000	mg/dl	132	179.404	6.7	1.30	19.95	-0.22	120	-2.45
7	175.000	mg/dl	126	162.088	6.4	1.14	18.03	0.72	86	7.97
8	228.000	mg/dl	127	203.582	6.6	1.48	22.64	1.08	68	11.99
9	143.000	mg/dl	132	139.286	6.7	1.02	15.49	0.24	120	2.67
10	190.000	mg/dl	140	176.264	7.3	1.35	19.61	0.70	87	7.79
11	139.000	mg/dl	133	139.526	6.5	0.97	15.52	-0.03	120	-0.38
12	204.000	mg/dl	134	202.507	6.3	1.38	22.53	0.07	120	0.74

	Cycle 10	Cycle 11
Cycle Average SDI	0.70	0.70
Cycle Average TS	90	90
Cycle Average %DEV	9.21	7.77
Cycle Average Absolute SDI	0.70	0.75
Cycle Average Absolute %DEV	9.21	8.33



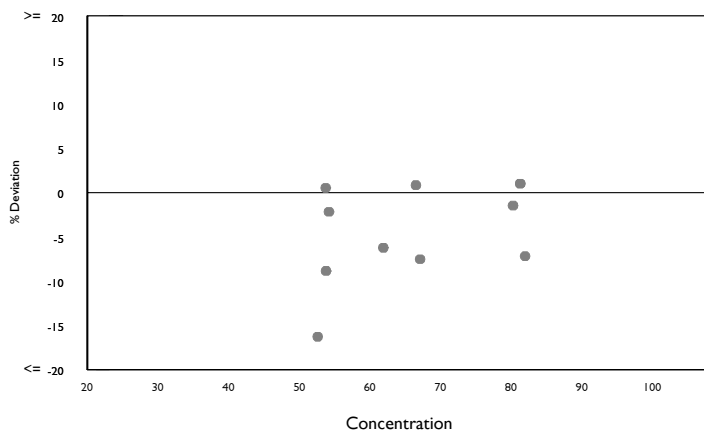
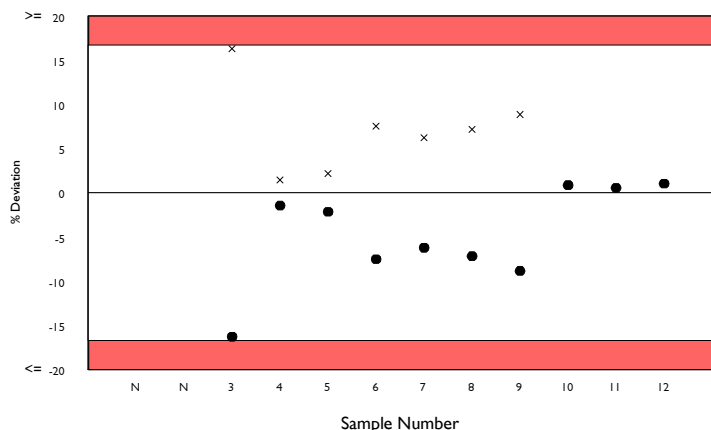
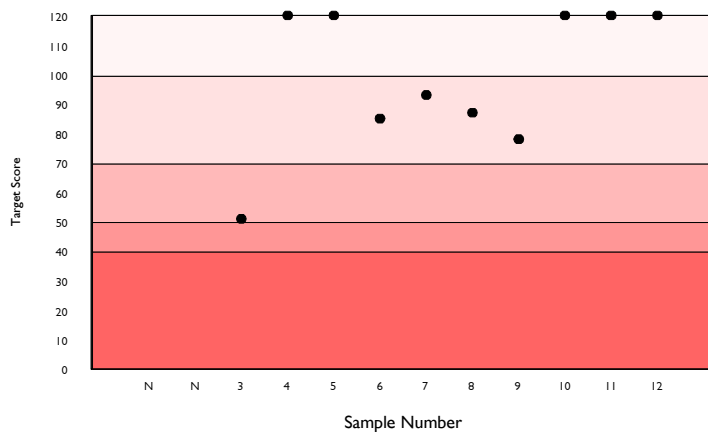
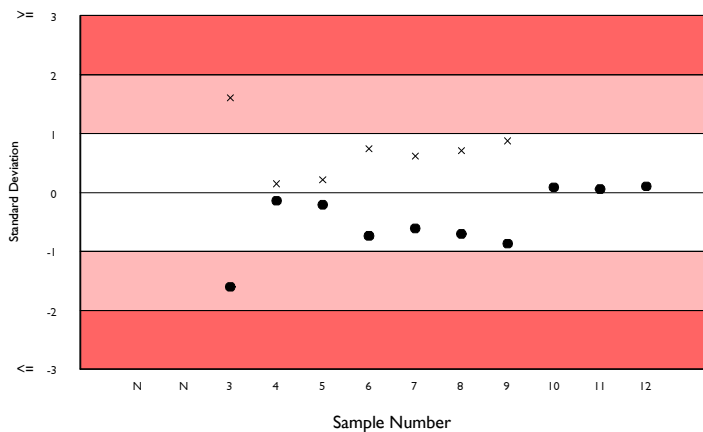
Antithrombin III activity, %

Method: HemosIL Liquid Antithrombin
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 16.7% **Biological Variation:** 8.3%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	%	56	66.787	5.7	0.63	6.78			
2	No Result	%	86	81.068	5.6	0.61	8.23			
3	44.000	%	112	52.558	7.7	0.48	5.34	-1.60	51	-16.28
4	79.000	%	114	80.164	6.5	0.61	8.14	-0.14	120	-1.45
5	53.000	%	112	54.167	7.1	0.45	5.50	-0.21	120	-2.15
6	62.000	%	104	67.039	4.9	0.40	6.81	-0.74	85	-7.52
7	58.000	%	112	61.852	4.9	0.36	6.28	-0.61	93	-6.23
8	76.000	%	115	81.869	4.8	0.45	8.31	-0.71	87	-7.17
9	49.000	%	118	53.756	6.3	0.39	5.46	-0.87	78	-8.85
10	67.000	%	113	66.431	6.0	0.46	6.74	0.08	120	0.86
11	54.000	%	117	53.708	7.4	0.46	5.45	0.05	120	0.54
12	82.000	%	118	81.168	4.6	0.43	8.24	0.10	120	1.03

	Cycle 10	Cycle 11
Cycle Average SDI	-0.16	-0.47
Cycle Average TS	105	99
Cycle Average %DEV	-1.54	-4.72
Cycle Average Absolute SDI	0.45	0.51
Cycle Average Absolute %DEV	4.36	5.21



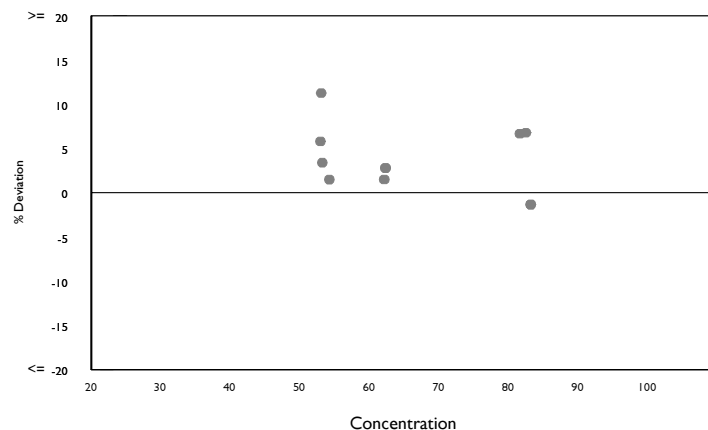
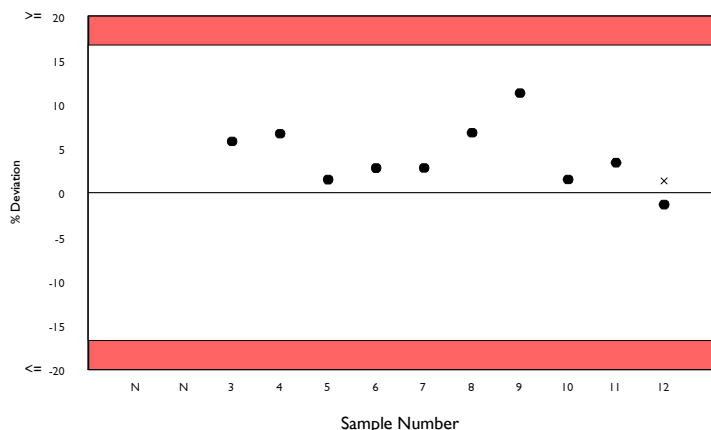
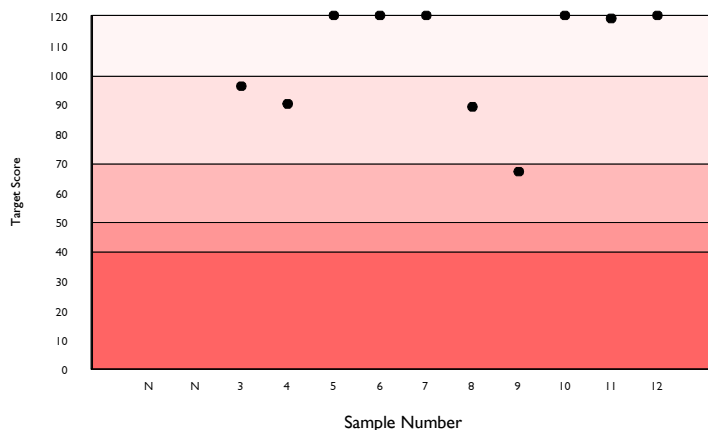
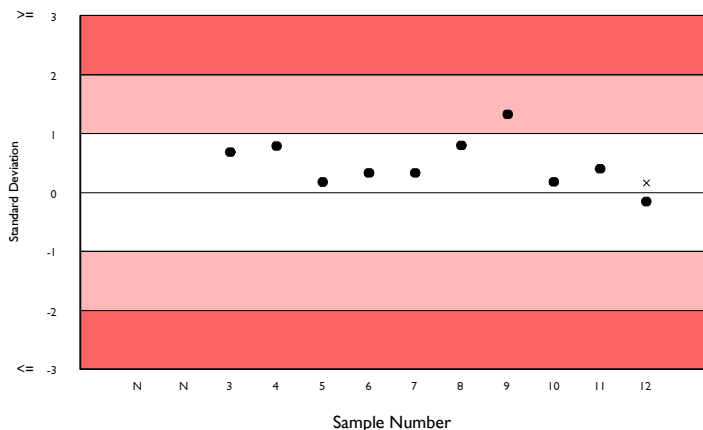
Protein C activity, %

Method: IL HemosIL Protein C
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 16.7% **Biological Variation:** 18.7%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	%	34	61.019	4.0	0.53	5.20			
2	No Result	%	53	80.964	3.9	0.54	6.90			
3	56.000	%	65	52.930	4.9	0.41	4.51	0.68	96	5.80
4	87.000	%	70	81.552	4.3	0.53	6.95	0.78	90	6.68
5	55.000	%	66	54.196	4.0	0.33	4.62	0.17	120	1.48
6	64.000	%	68	62.260	4.1	0.39	5.30	0.33	120	2.79
7	64.000	%	70	62.255	3.9	0.37	5.30	0.33	120	2.80
8	88.000	%	68	82.415	4.8	0.60	7.02	0.80	89	6.78
9	59.000	%	68	53.023	4.7	0.38	4.52	1.32	67	11.27
10	63.000	%	75	62.070	5.8	0.52	5.29	0.18	120	1.50
11	55.000	%	71	53.194	4.3	0.34	4.53	0.40	119	3.40
12	82.000	%	79	83.114	4.5	0.52	7.08	-0.16	120	-1.34

	Cycle 10	Cycle 11
Cycle Average SDI	-0.33	0.48
Cycle Average TS	116	106
Cycle Average %DEV	-2.67	4.12
Cycle Average Absolute SDI	0.33	0.51
Cycle Average Absolute %DEV	2.67	4.38



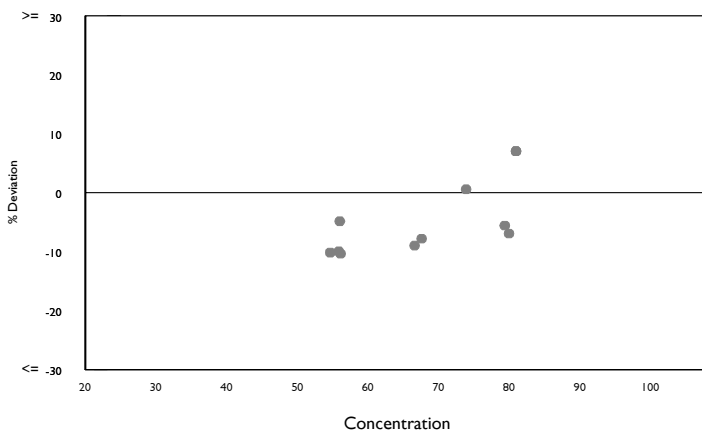
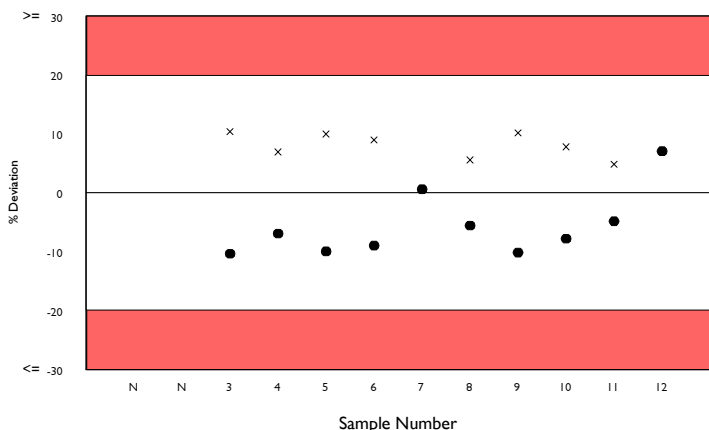
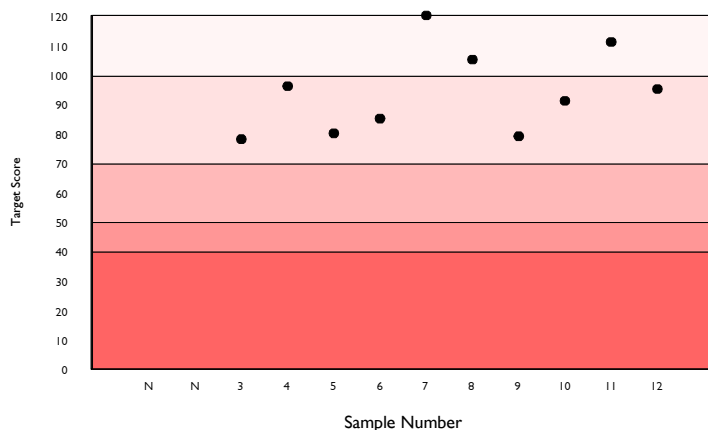
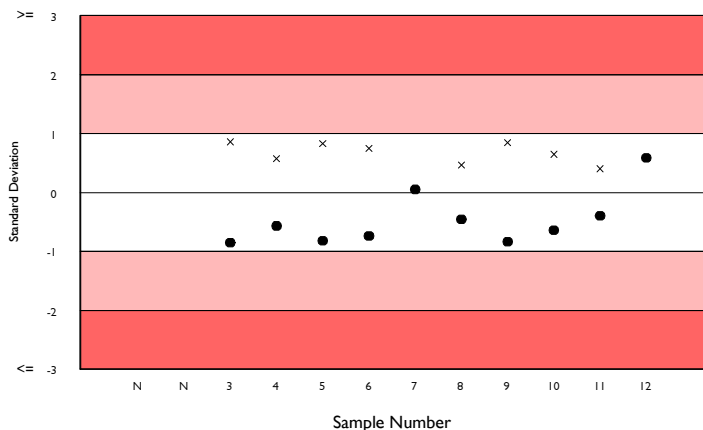
Protein S activity, %

Method: IL HemosIL Free Protein S
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 19.9% **Biological Variation:** 20.7%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	%	23	69.332	6.2	1.12	8.39			
2	No Result	%	33	80.021	7.4	1.28	9.68			
3	50.300	%	41	56.105	8.4	0.92	6.79	-0.86	78	-10.35
4	74.400	%	45	79.929	5.1	0.75	9.67	-0.57	96	-6.92
5	50.300	%	42	55.865	4.3	0.47	6.76	-0.82	80	-9.96
6	60.600	%	47	66.574	6.2	0.75	8.05	-0.74	85	-8.97
7	74.300	%	43	73.863	5.0	0.71	8.94	0.05	120	0.59
8	74.900	%	49	79.316	6.4	0.91	9.60	-0.46	105	-5.57
9	49.100	%	45	54.651	5.2	0.53	6.61	-0.84	79	-10.16
10	62.300	%	49	67.563	6.1	0.74	8.17	-0.64	91	-7.79
11	53.300	%	45	56.009	5.7	0.60	6.78	-0.40	111	-4.84
12	86.600	%	51	80.896	4.7	0.66	9.79	0.58	95	7.05

	Cycle 10	Cycle 11
Cycle Average SDI	-0.07	-0.47
Cycle Average TS	117	94
Cycle Average %DEV	-1.28	-5.69
Cycle Average Absolute SDI	0.20	0.60
Cycle Average Absolute %DEV	3.57	7.22



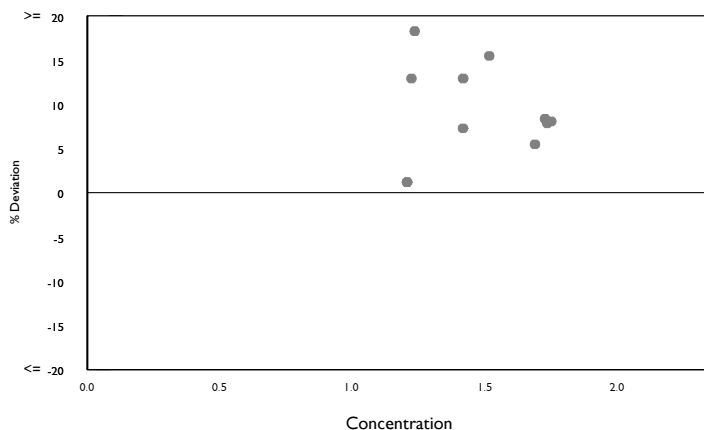
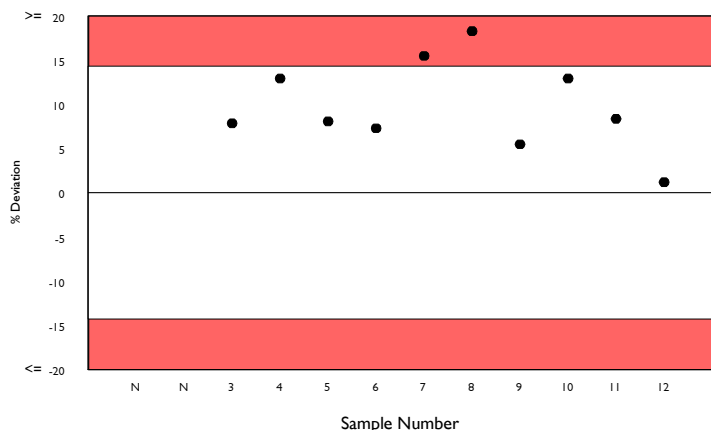
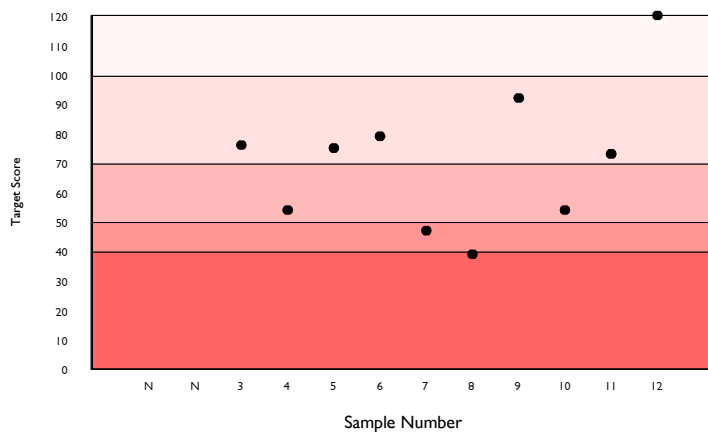
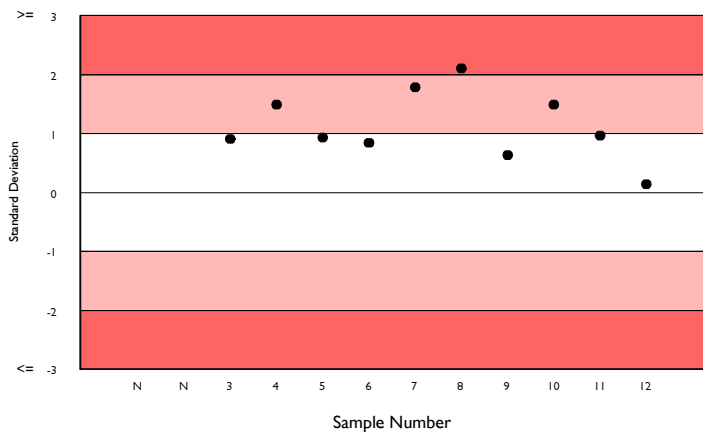
aPTT as a ratio, RATIO

Method: HemosIL APTT-SP liquid
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 14.3% **Biological Variation:** 4.5%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	RATIO	60	1.429	5.9	0.01	0.12			
2	No Result	RATIO	71	1.223	3.7	0.01	0.11			
3	1.870	RATIO	78	1.734	4.9	0.01	0.15	0.90	76	7.85
4	1.380	RATIO	82	1.222	4.8	0.01	0.11	1.49	54	12.93
5	1.890	RATIO	82	1.749	5.6	0.01	0.15	0.93	75	8.07
6	1.520	RATIO	82	1.417	4.8	0.01	0.12	0.84	79	7.29
7	1.750	RATIO	83	1.515	6.2	0.01	0.13	1.78	47	15.48
8	1.460	RATIO	80	1.235	4.3	0.01	0.11	2.10	39	18.27
9	1.780	RATIO	82	1.688	4.9	0.01	0.15	0.63	92	5.48
10	1.600	RATIO	78	1.417	4.6	0.01	0.12	1.49	54	12.92
11	1.870	RATIO	78	1.726	4.7	0.01	0.15	0.96	73	8.36
12	1.220	RATIO	76	1.206	4.0	0.01	0.10	0.14	120	1.19

	Cycle 10	Cycle 11
Cycle Average SDI	1.07	1.13
Cycle Average TS	75	71
Cycle Average %DEV	10.68	9.78
Cycle Average Absolute SDI	1.07	1.13
Cycle Average Absolute %DEV	10.68	9.78



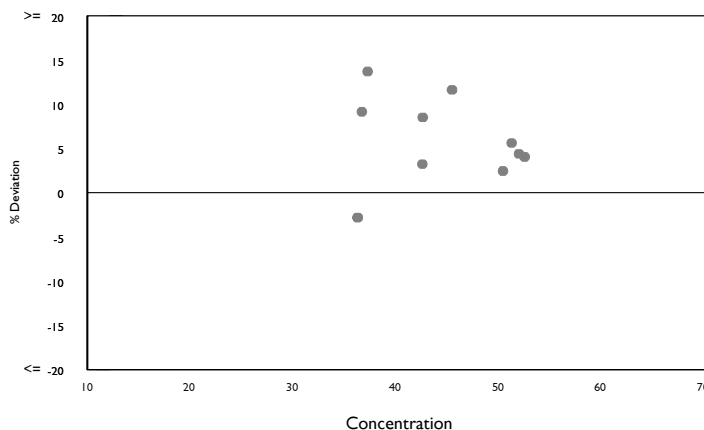
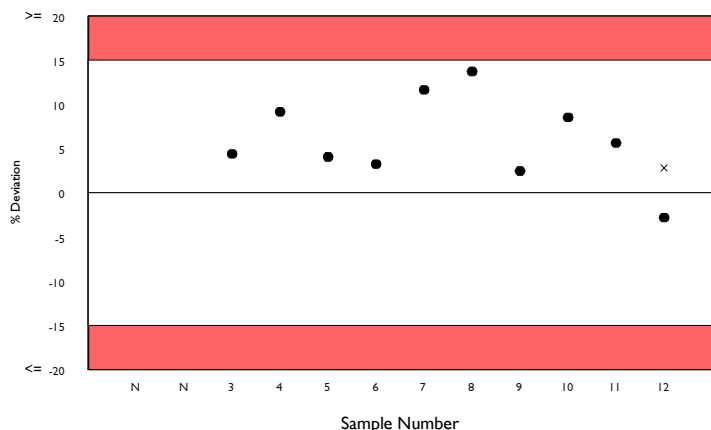
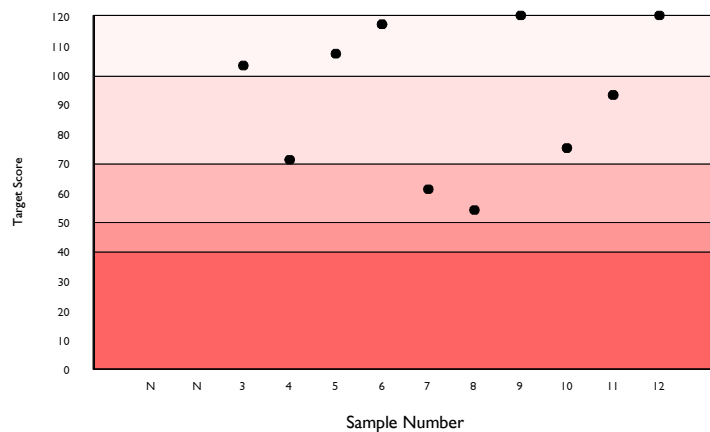
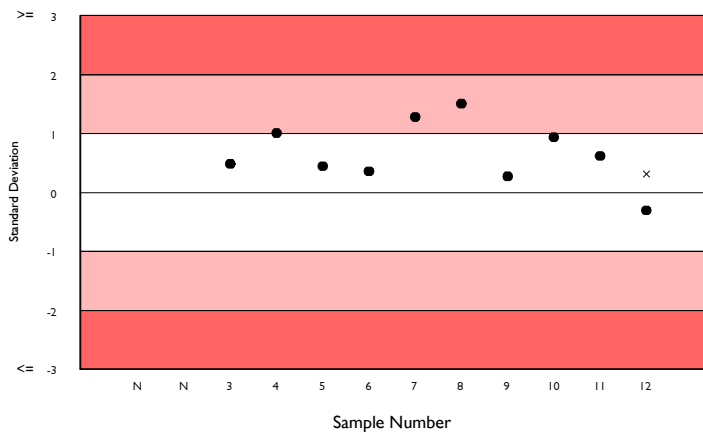
aPTT in seconds, s

Method: HemosIL APTT-SP liquid
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 15% **Biological Variation:** 4.5%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	s	132	43.236	4.6	0.22	3.94			
2	No Result	s	174	36.796	3.1	0.11	3.36			
3	54.300	s	187	52.016	4.8	0.23	4.74	0.48	103	4.39
4	40.100	s	192	36.735	3.0	0.10	3.35	1.00	71	9.16
5	54.700	s	192	52.571	4.4	0.21	4.79	0.44	107	4.05
6	44.000	s	197	42.620	4.3	0.16	3.89	0.36	117	3.24
7	50.800	s	201	45.503	5.5	0.22	4.15	1.28	61	11.64
8	42.400	s	199	37.287	3.8	0.12	3.40	1.50	54	13.71
9	51.700	s	200	50.459	4.8	0.21	4.60	0.27	120	2.46
10	46.300	s	193	42.665	3.8	0.14	3.89	0.93	75	8.52
11	54.200	s	196	51.313	4.4	0.20	4.68	0.62	93	5.63
12	35.300	s	193	36.316	3.6	0.12	3.31	-0.31	120	-2.80

	Cycle 10	Cycle 11
Cycle Average SDI	0.67	0.66
Cycle Average TS	93	92
Cycle Average %DEV	7.05	6.00
Cycle Average Absolute SDI	0.70	0.72
Cycle Average Absolute %DEV	7.43	6.56



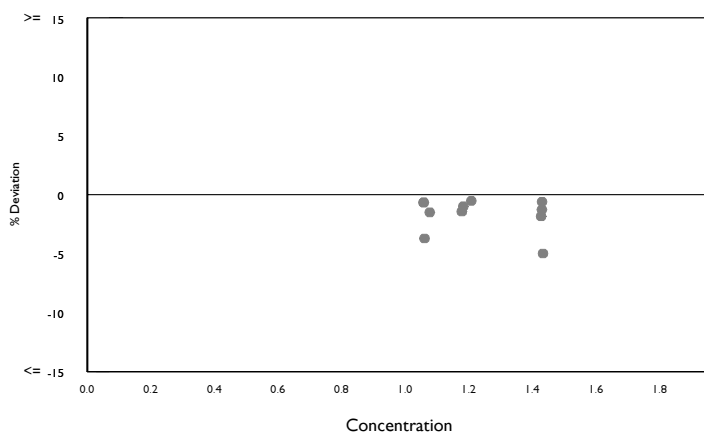
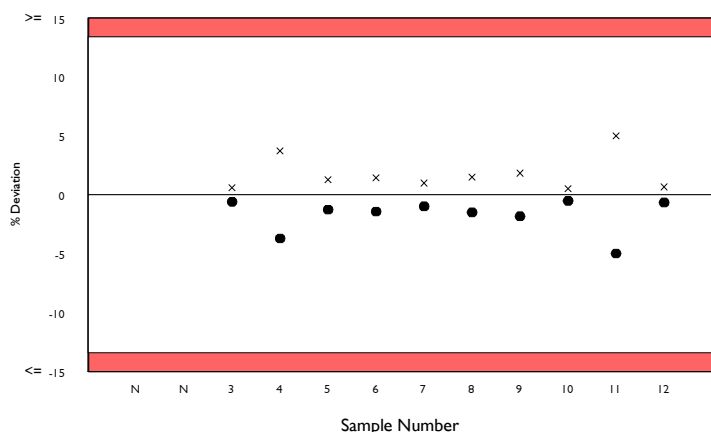
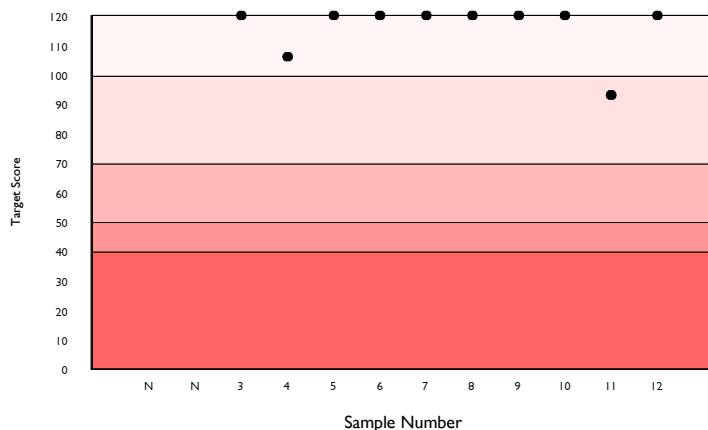
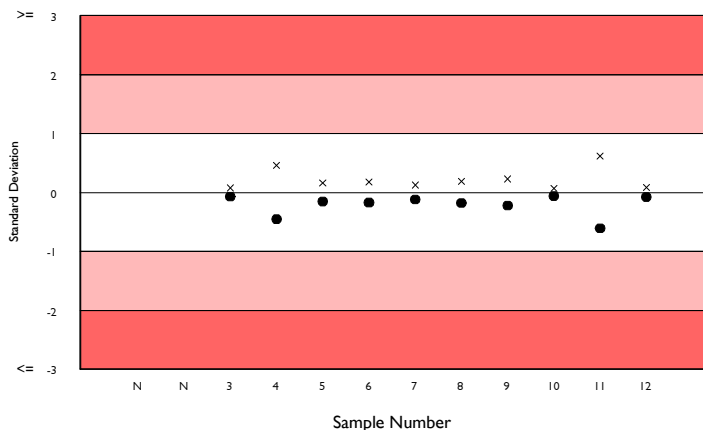
PT as an INR, INR

Method: HemosIL RecombiPlasTin 2G
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 13.4% **Biological Variation:** 5.3%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	INR	208	1.220	5.0	0.01	0.10			
2	No Result	INR	282	1.059	3.9	0.00	0.09			
3	1.420	INR	292	1.429	4.1	0.00	0.12	-0.07	120	-0.60
4	1.020	INR	318	1.059	3.9	0.00	0.09	-0.46	106	-3.71
5	1.410	INR	312	1.428	4.0	0.00	0.12	-0.16	120	-1.27
6	1.160	INR	321	1.177	4.1	0.00	0.10	-0.18	120	-1.43
7	1.170	INR	315	1.182	4.0	0.00	0.10	-0.12	120	-0.99
8	1.060	INR	316	1.076	3.7	0.00	0.09	-0.18	120	-1.50
9	1.400	INR	319	1.426	3.9	0.00	0.12	-0.22	120	-1.83
10	1.200	INR	326	1.206	4.1	0.00	0.10	-0.06	120	-0.52
11	1.360	INR	321	1.431	4.0	0.00	0.12	-0.61	93	-4.99
12	1.050	INR	319	1.057	3.8	0.00	0.09	-0.08	120	-0.66

	Cycle 10	Cycle 11
Cycle Average SDI	-0.32	-0.21
Cycle Average TS	108	116
Cycle Average %DEV	-2.84	-1.75
Cycle Average Absolute SDI	0.41	0.21
Cycle Average Absolute %DEV	3.61	1.75



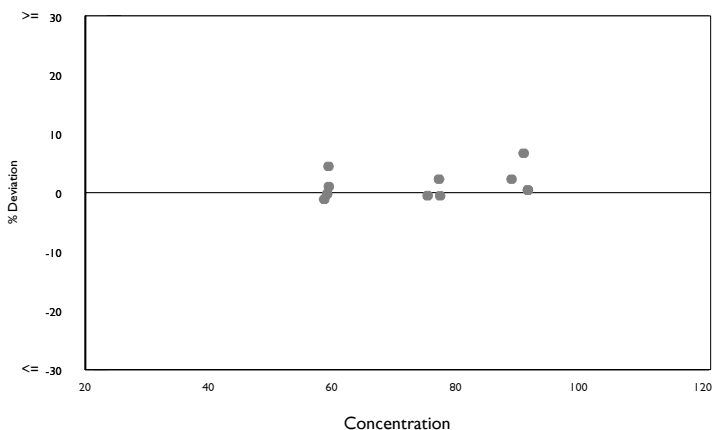
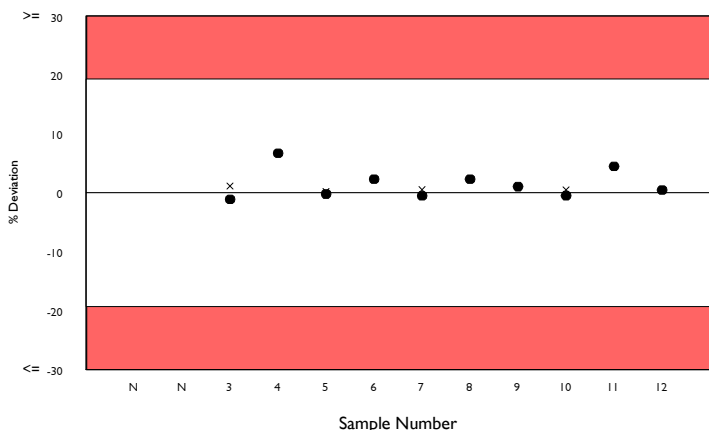
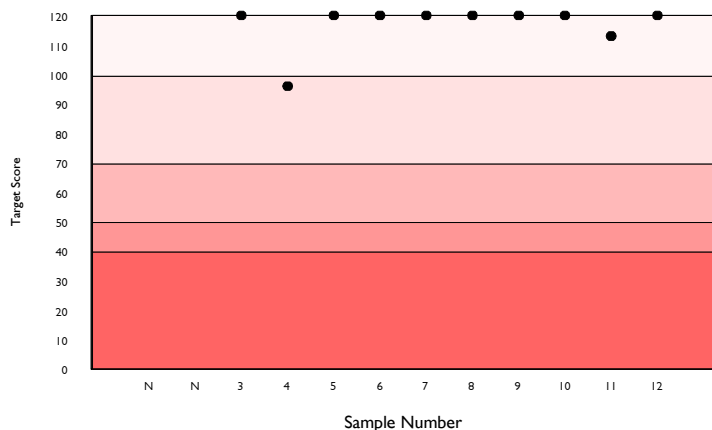
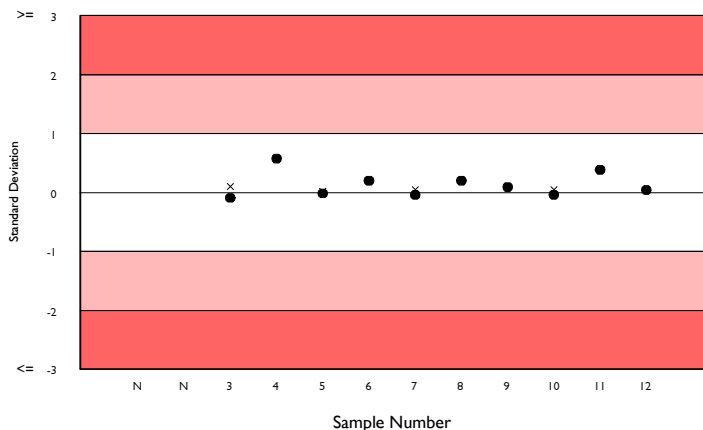
PT activity, %

Method: HemosIL RecombiPlasTin 2G
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 19.3% **Biological Variation:** 5.3%

Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	%	129	73.764	5.0	0.41	8.66			
2	No Result	%	150	91.490	4.8	0.45	10.74			
3	58.000	%	158	58.661	4.9	0.29	6.88	-0.10	120	-1.13
4	97.000	%	163	90.902	5.3	0.48	10.67	0.57	96	6.71
5	59.000	%	164	59.128	4.5	0.26	6.94	-0.02	120	-0.22
6	79.000	%	161	77.227	5.2	0.39	9.06	0.20	120	2.30
7	77.000	%	168	77.404	5.2	0.39	9.08	-0.04	120	-0.52
8	91.000	%	166	88.950	5.7	0.50	10.44	0.20	120	2.30
9	60.000	%	166	59.385	4.8	0.28	6.97	0.09	120	1.04
10	75.000	%	170	75.373	5.7	0.41	8.84	-0.04	120	-0.50
11	62.000	%	165	59.347	4.9	0.28	6.96	0.38	113	4.47
12	92.000	%	164	91.585	5.5	0.49	10.75	0.04	120	0.45

	Cycle 10	Cycle 11
Cycle Average SDI	0.18	0.13
Cycle Average TS	111	117
Cycle Average %DEV	2.21	1.49
Cycle Average Absolute SDI	0.33	0.17
Cycle Average Absolute %DEV	4.07	1.96



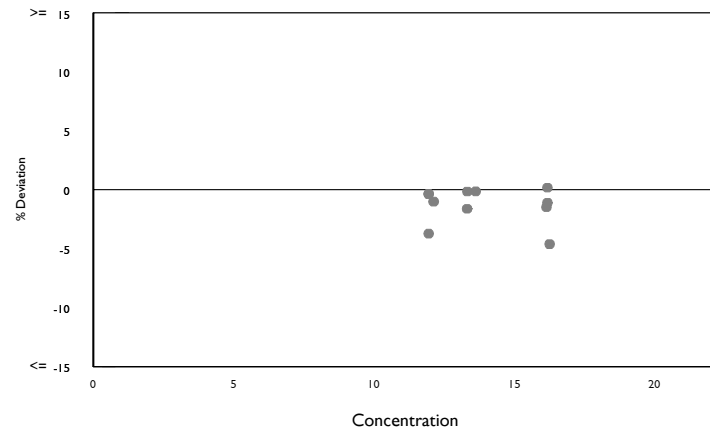
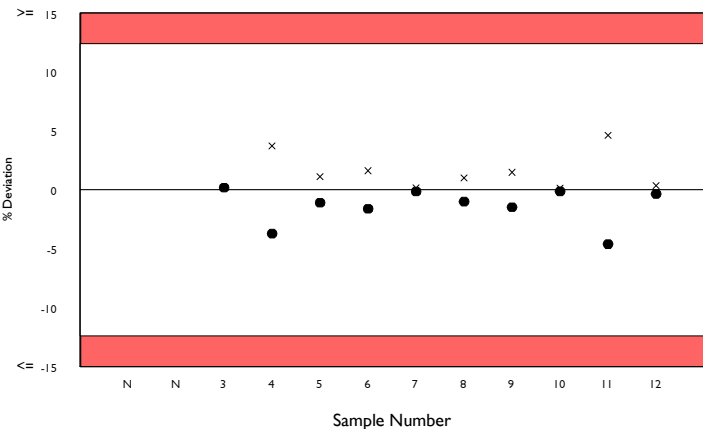
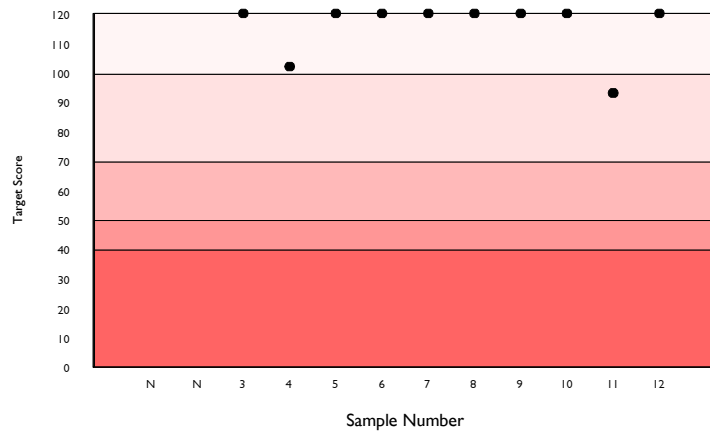
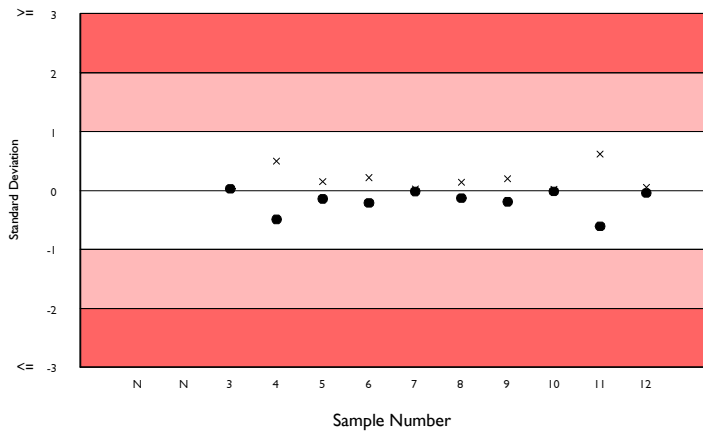
PT in seconds, s

Method: HemosIL RecombiPlasTin 2G
Instrument: IL ACL TOP
Reagent: Instrumentation Laboratories (IL)

RIQAS TDPA: 12.4% **Biological Variation:** 5.3%

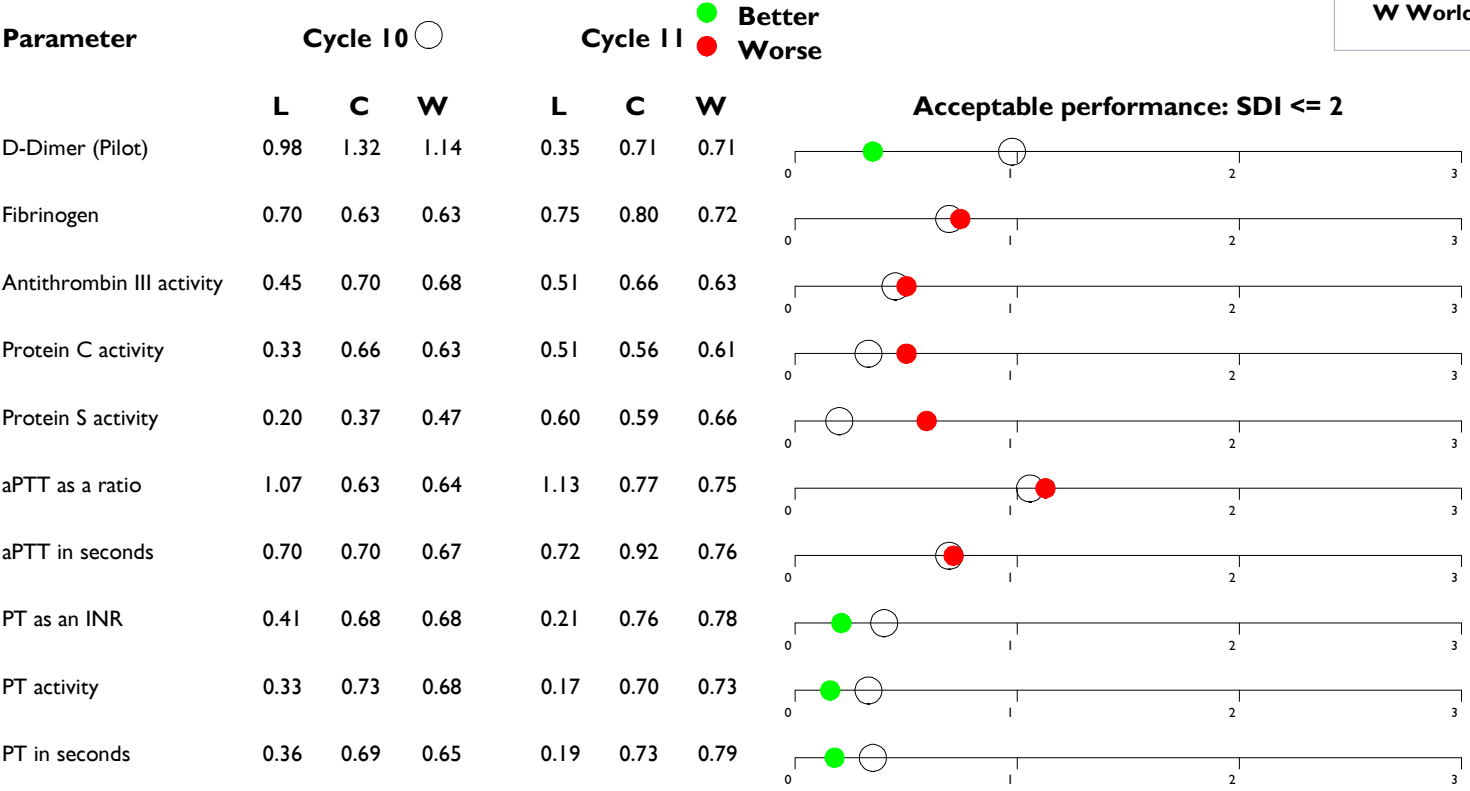
Sample	Result	Unit	N	Mean for Comparison	CV%	Um	SDPA	SDI	TS	%Deviation
1	No Result	s	195	13.676	3.5	0.04	1.03			
2	No Result	s	275	11.937	2.5	0.02	0.90			
3	16.200	s	292	16.171	2.6	0.03	1.22	0.02	120	0.18
4	11.500	s	315	11.945	2.9	0.02	0.90	-0.49	102	-3.72
5	16.000	s	298	16.178	2.1	0.02	1.22	-0.15	120	-1.10
6	13.100	s	315	13.315	3.0	0.03	1.00	-0.21	120	-1.61
7	13.300	s	311	13.321	2.7	0.03	1.00	-0.02	120	-0.15
8	12.000	s	303	12.122	2.4	0.02	0.91	-0.13	120	-1.01
9	15.900	s	309	16.139	2.4	0.03	1.22	-0.20	120	-1.48
10	13.600	s	320	13.619	3.0	0.03	1.03	-0.02	120	-0.14
11	15.500	s	317	16.249	2.4	0.03	1.22	-0.61	93	-4.61
12	11.900	s	318	11.942	2.7	0.02	0.90	-0.05	120	-0.36

	Cycle 10	Cycle 11
Cycle Average SDI	-0.26	-0.19
Cycle Average TS	109	116
Cycle Average %DEV	-2.31	-1.40
Cycle Average Absolute SDI	0.36	0.19
Cycle Average Absolute %DEV	3.18	1.44



Cycle Average Absolute SDI

L Laboratory
C Country
W World



END OF REPORT



CERTIFICATE OF ACCEPTABLE PERFORMANCE

Biolab SRL
Via Igea 12C
ROMA
00135
ITALY

LABORATORY REF. NO. 260037/A

COAGULATION - CYCLE II

16/12/2019

This is to certify that the above participant took part in a cycle of external quality assessment and achieved an acceptable level of performance (Cycle Average Absolute SDI ≤ 2) for the following parameters:

	Cycle Average Absolute SDI
D-Dimer (Pilot) - Biomerieux VIDAS Exclusion II - Biomerieux Vidas/miniVidas/Vidas 3	0.35
Fibrinogen - HemosIL QFA (bovine thrombin) - IL ACL TOP	0.75
Antithrombin III activity - HemosIL Liquid Antithrombin - IL ACL TOP	0.51
Protein C activity - IL HemosIL Protein C - IL ACL TOP	0.51
Protein S activity - IL HemosIL Free Protein S - IL ACL TOP	0.60
aPTT as a ratio - HemosIL APTT-SP liquid - IL ACL TOP	1.13
aPTT in seconds - HemosIL APTT-SP liquid - IL ACL TOP	0.72
PT as an INR - HemosIL RecombiPlasTin 2G - IL ACL TOP	0.21
PT activity - HemosIL RecombiPlasTin 2G - IL ACL TOP	0.17
PT in seconds - HemosIL RecombiPlasTin 2G - IL ACL TOP	0.19

This certificate is valid until 17/01/2021

Authorised by:
Stephen Doherty, RIQAS Manager

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