



QC SEROLOGY INVESTIGATION PMM-QC-587

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1 Introduction

An investigation was requested by Participant 43 into the reactivity of QConnect HIVp24 DM17089 when tested in the Abbott ARCHITECT HIV Ag/Ab Combo CMIA. The participant was concerned about imprecision (fluctuation in the results observed), supported by elevated %CV. NRL had agreed to look into all participant data to see if there were any patterns or root cause that could explain these results.

2 Findings

- Figure 1 – Scatter chart showing all data for all laboratories for QC lot DM17085
- Figure 2 – LJ chart for Lab 145 showing data within NRL Limits by reagent lot
- Figure 3 – LJ chart for Lab 1015 showing data within NRL Limits by reagent lot
- Figure 4 – LJ chart for Lab 938 showing data within NRL Limits by reagent lot
- Figure 5 – LJ chart for Lab 8 showing data within NRL Limits by reagent lot
- Figure 6 – LJ chart for Lab 43 showing data within NRL Limits linking all data
- Figure 7 – LJ chart for Lab 43 showing data within NRL Limits by operator
- Figure 8 – LJ chart for Lab 43 showing data within NRL Limits by instrument
- Figure 9 – LJ chart for Lab 43 showing data within NRL Limits by reagent lot
- Figure 10 – Scatter chart showing all reagent lots for QC lot DM17085
- Table 1 – All summary data for QC lot DM17085 by laboratory
- Table 2 – All summary data for QC lot 158876 by laboratory
- Table 3 – All summary data for QC lot 160766 by laboratory
- Table 4 – All summary data for QC lot 169561 by laboratory
- Table 5 – All summary data for QC lot 334302 by laboratory
- Table 6 – All summary data for QC lot 416805 by laboratory
- Table 7 – All summary data for QC lot 425806 by laboratory
- Table 8 – All summary data for QC lot DM17085 by reagent lot

3 Conclusion

When data was investigated for QConnect HIVp24, NRL looked at all participants reporting results (Table 1). Examples of situations where %CV was both high and low were chosen to see if there were patterns evident. Overall, there was an elevated trend in %CV for participants reporting data for this QC lot, with the overall total %CV around 20. Some participants did report much higher rates, as high 31.34 (Participant 43 themselves) and 26.40 (Participant 938) but in general there were many reporting %CV in the 10-20 range. However, %CV over 15 is not typical in serology testing where the result mean was around S/Co 3.50 on average. Only two participants reported data outside the NRL QConnect Limits (Figure 1), coincidentally both the participants observing the highest %CV. Therefore the next step was to look at individual participant charts, and summary data for other QC lot numbers (Tables 2-7 and Figures 2-9).

Data reported by Participant 43 was looked at in a number of ways, such as by reagent lot, instrument and operator. All could be interpreted as identifying issues either by operator (Figure 7) instrument (Figure 8) or reagent lot, yet it is most likely that the reagent lot 78018LI00 has been a potential cause for greater variation. Other participant data do support this point (Table 8 and Figures 3, 9 and 10) but this is not

conclusive, and Table 8 confirms %CV was no greater for this reagent lot than any other.

Another point to consider is that all QC lot numbers, regardless of whether manufactured by Diamex or Thermo Fisher Scientific, demonstrated elevated levels of %CV when compared to the QC for the antibody component of the assay, QConnect Blue (Tables 2-7). Perhaps the variation seen is inherent with the antigen detection component of the test.

4 Recommendations

NRL recommends continuing to observe data generated to determine if the variation seen can be attributed to any other source. It is also NRLs opinion that the antigen detection component of the assay may be more prone to variation than the antibody component.

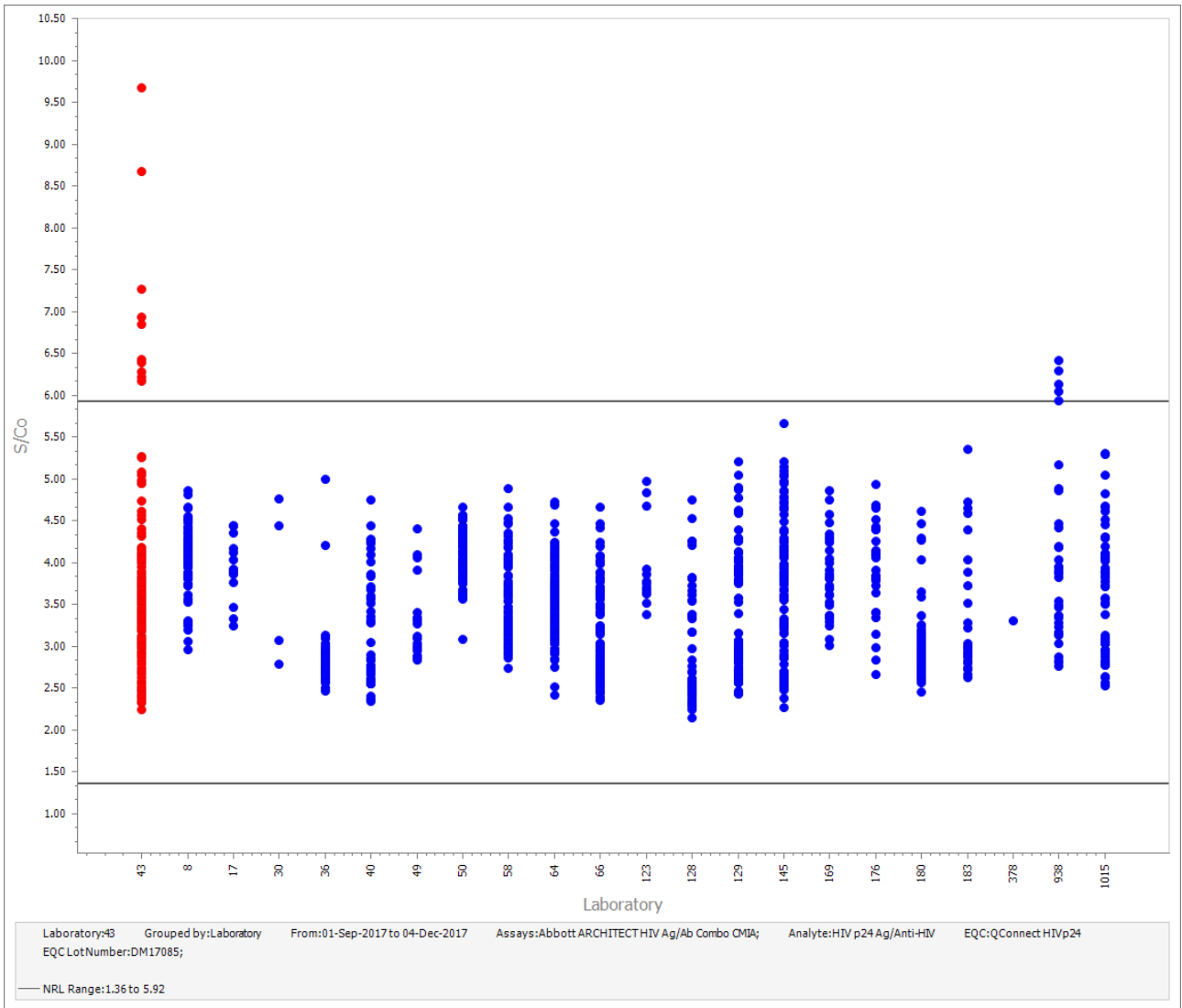


Figure 1

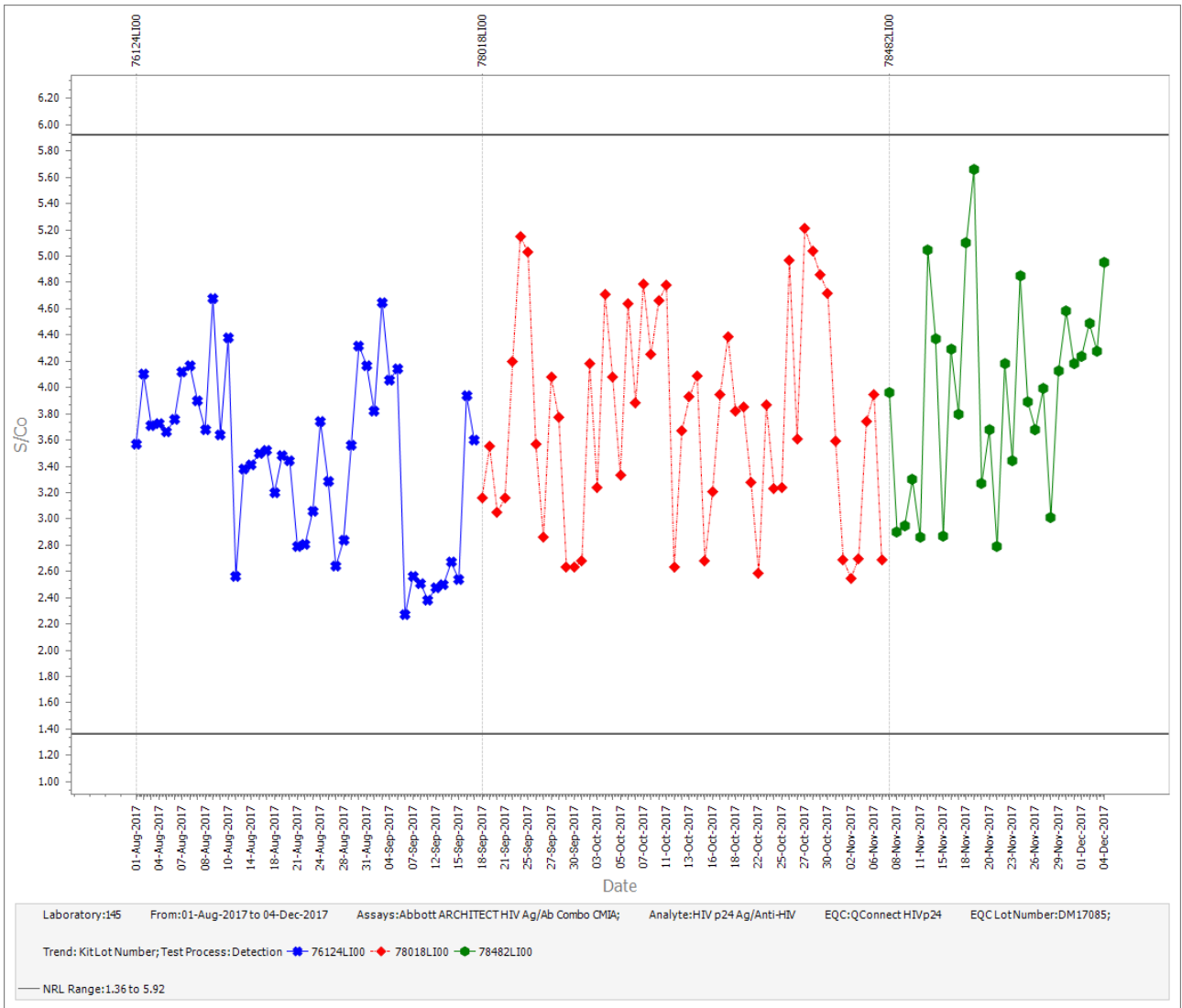


Figure 2

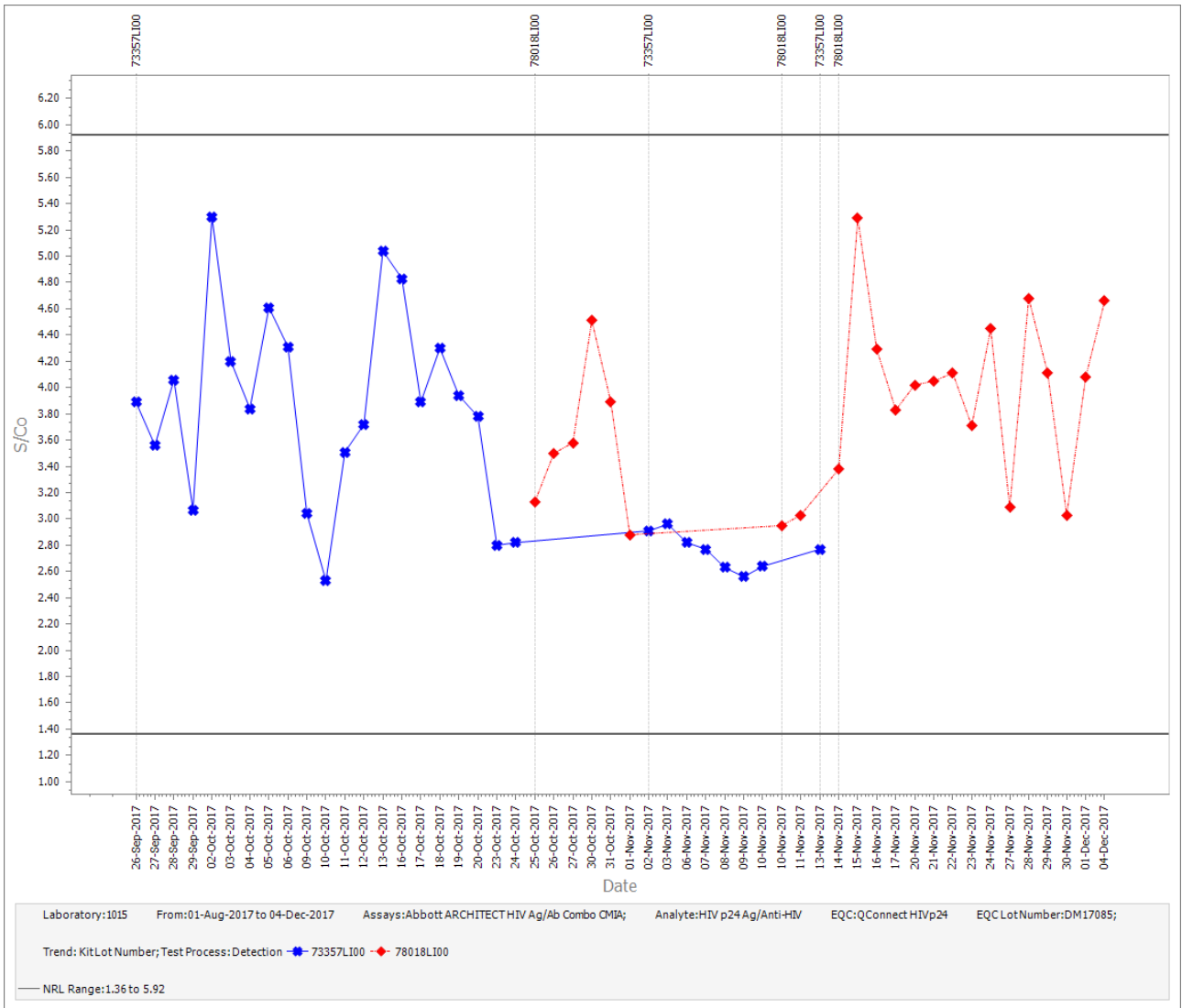


Figure 3

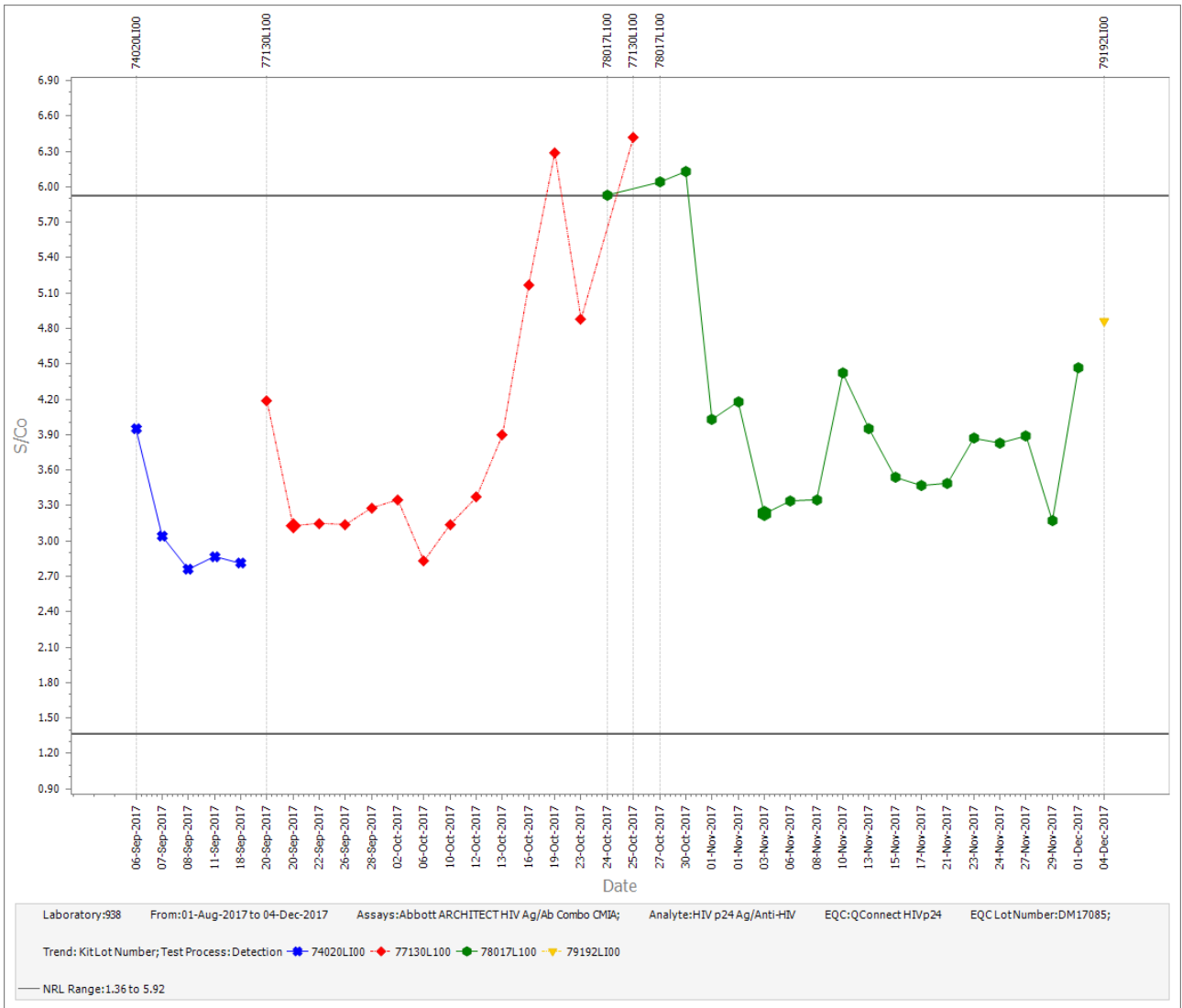


Figure 4

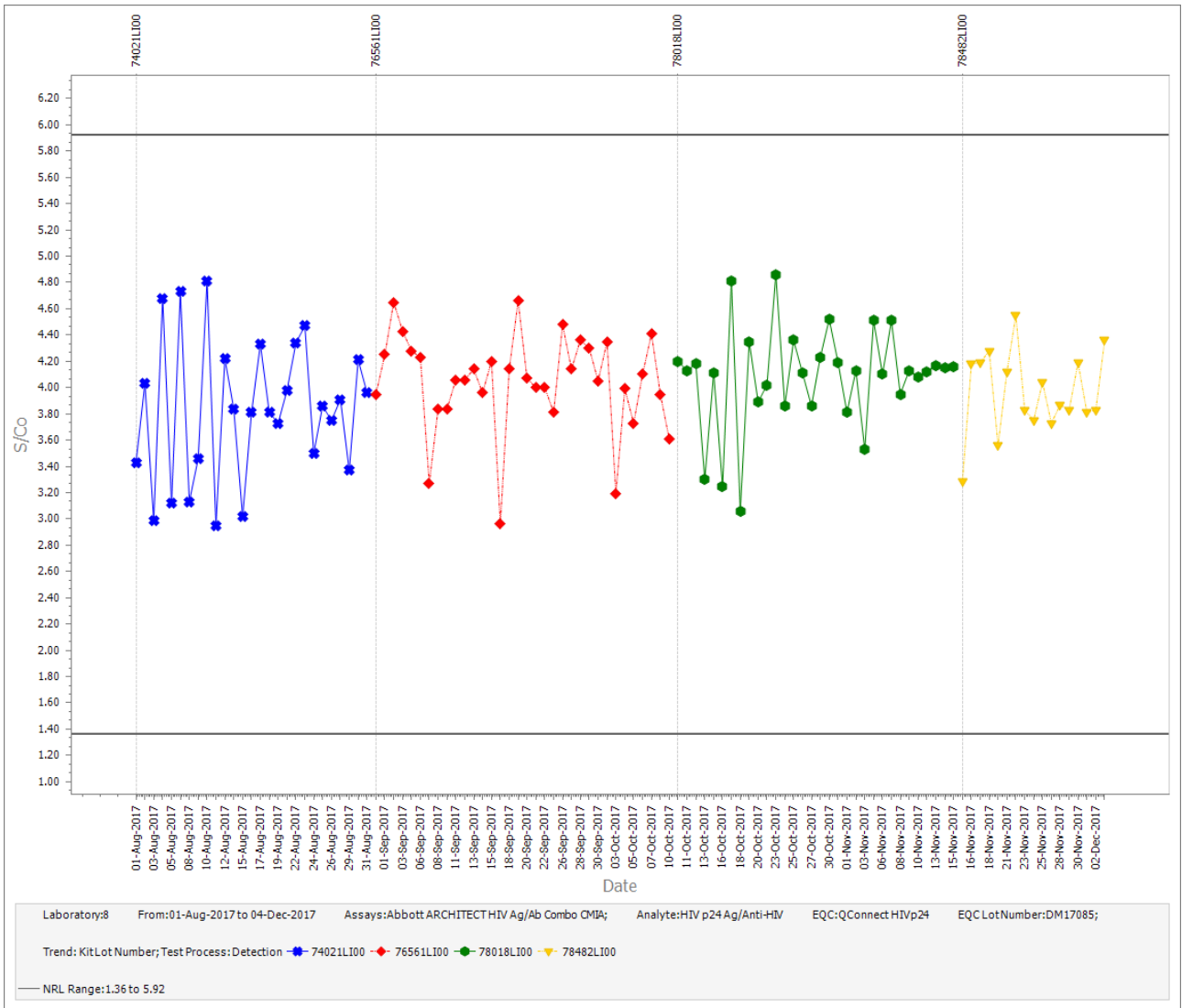


Figure 5

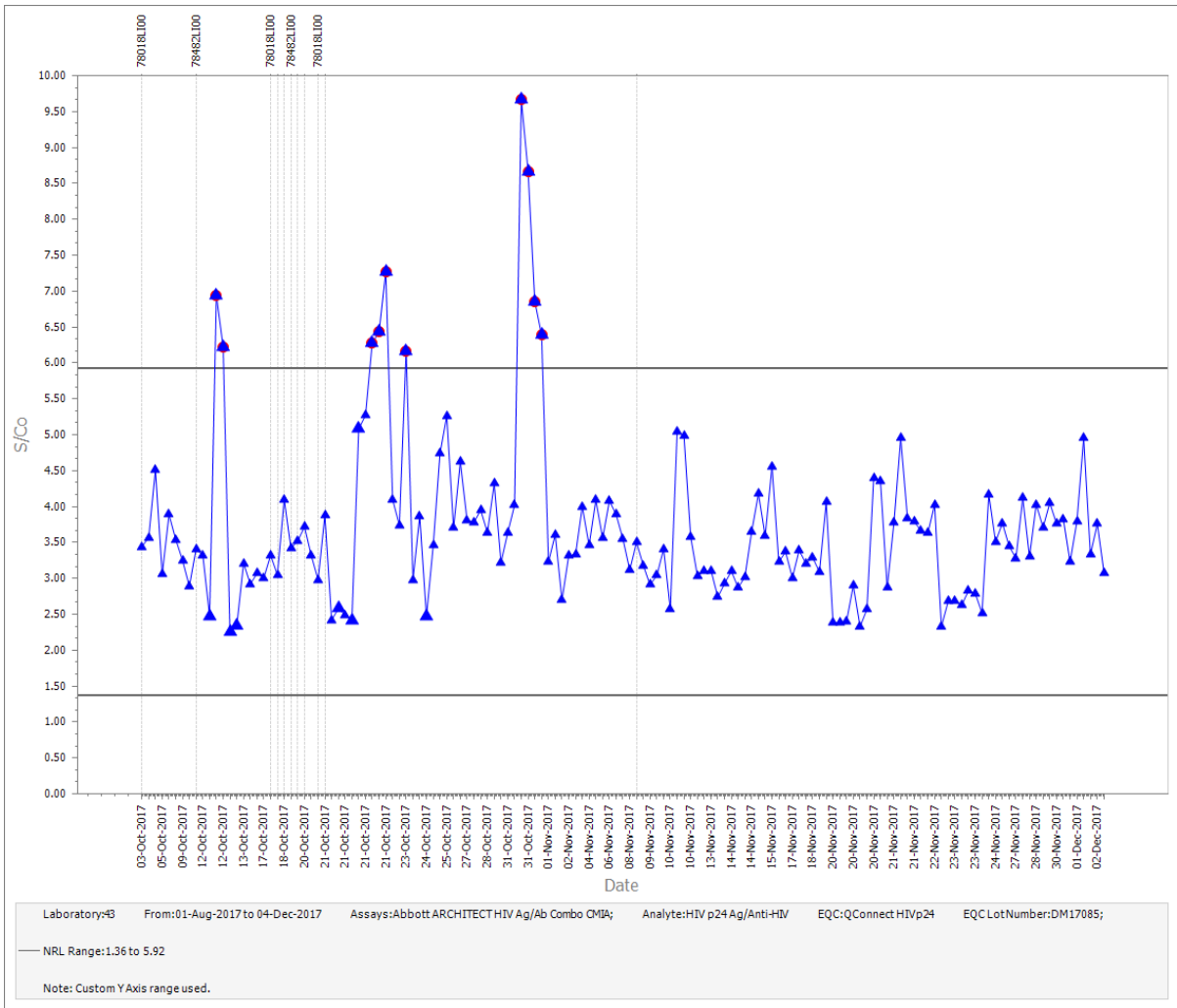


Figure 6

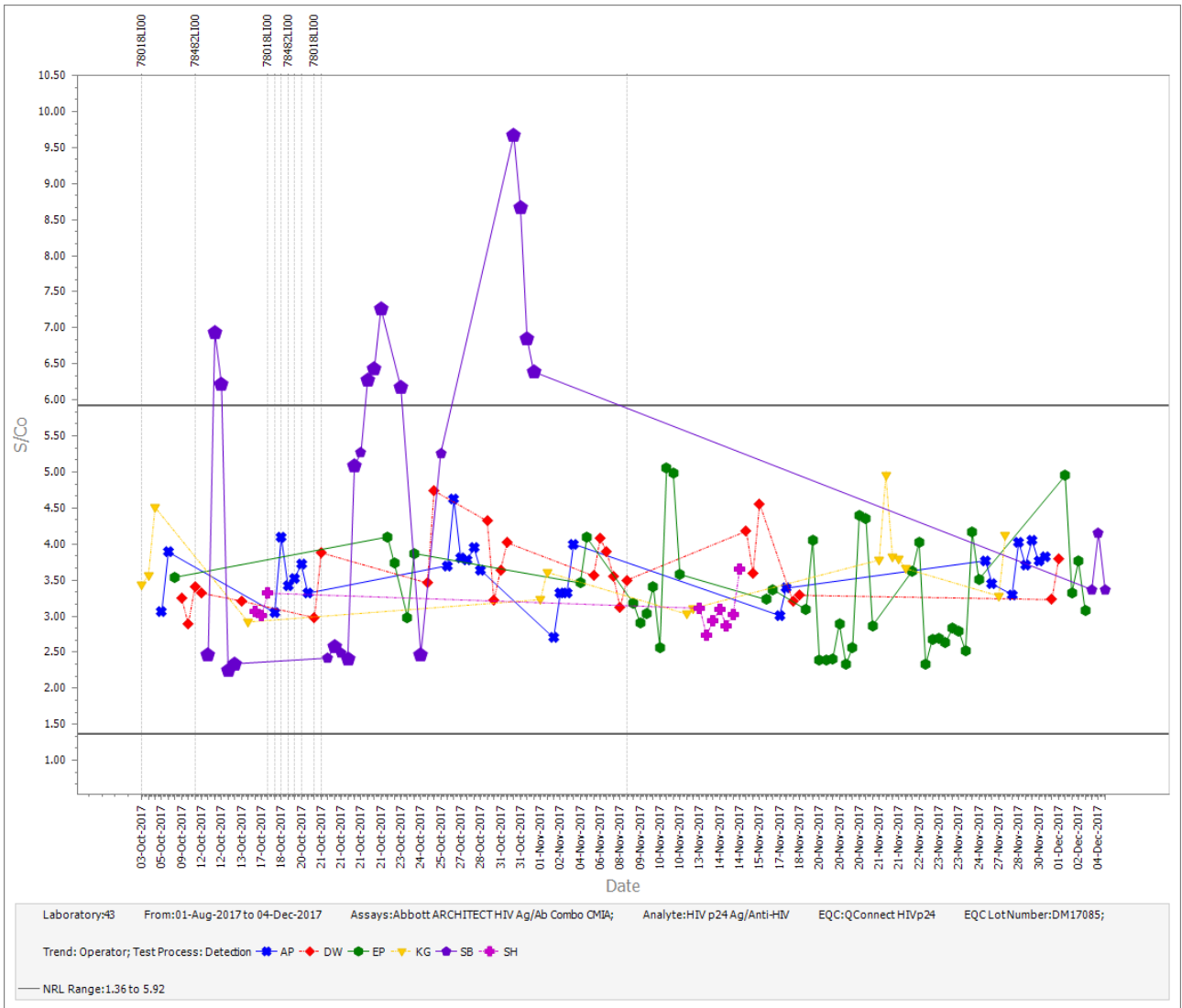


Figure 7

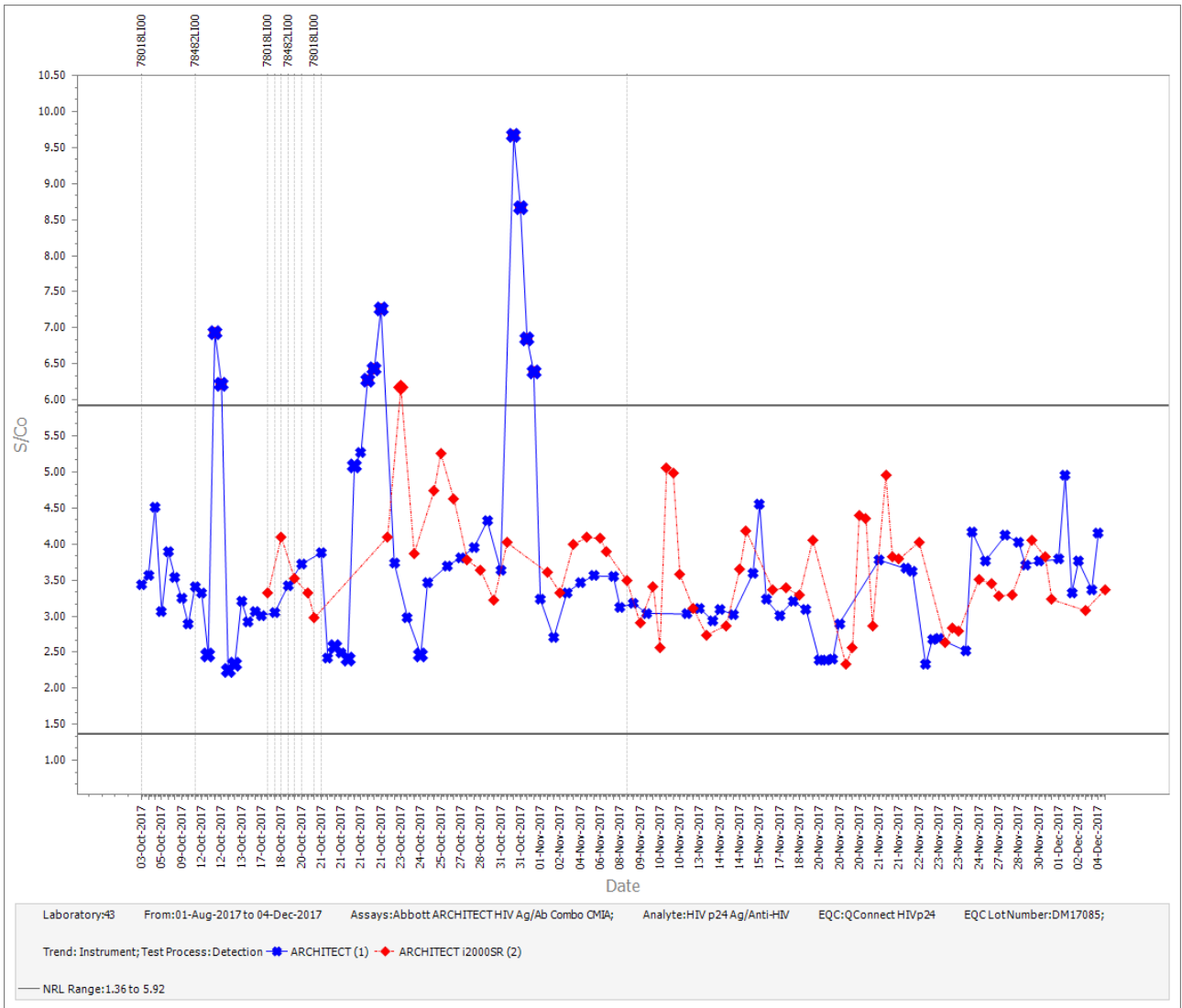


Figure 8

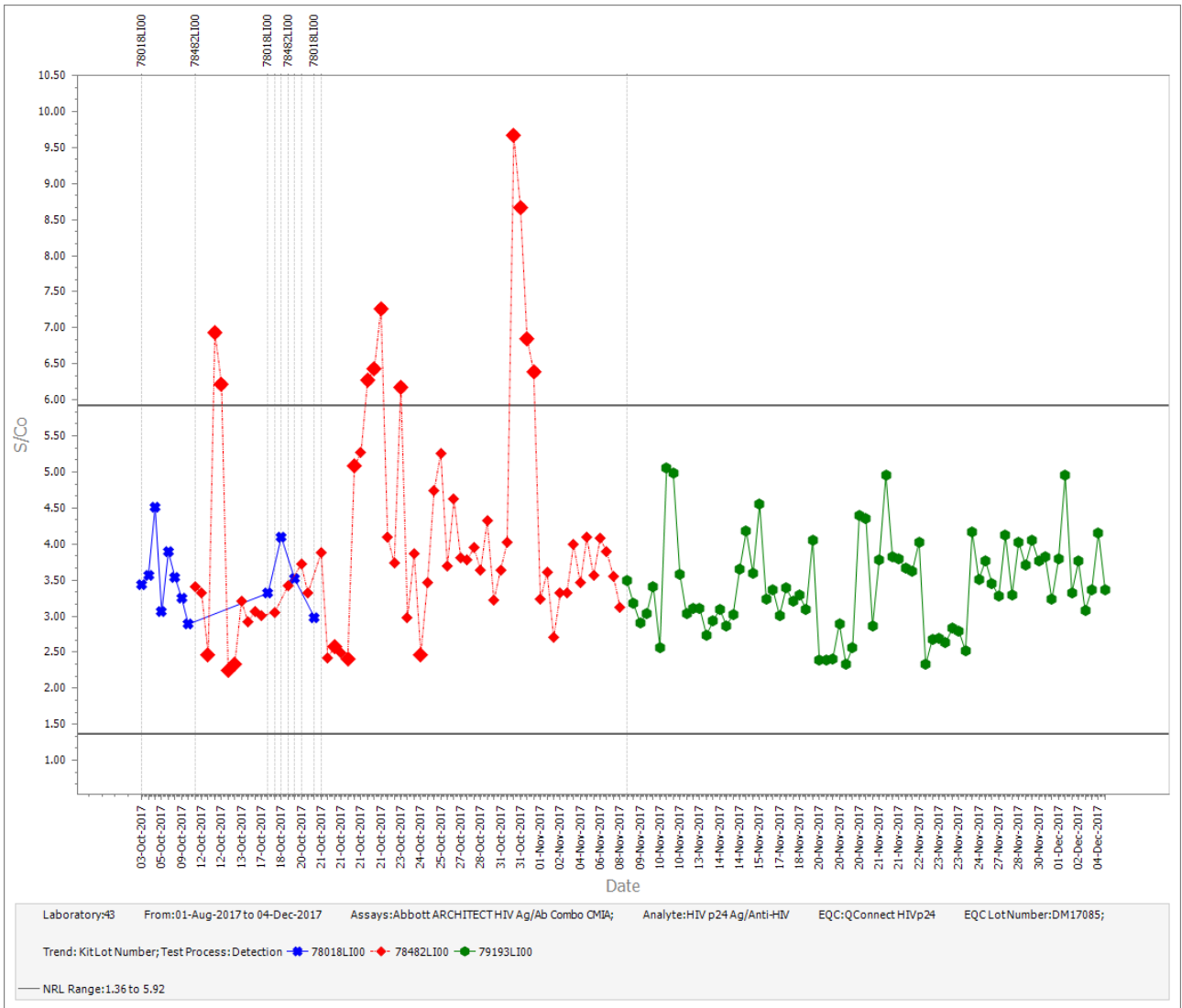


Figure 9

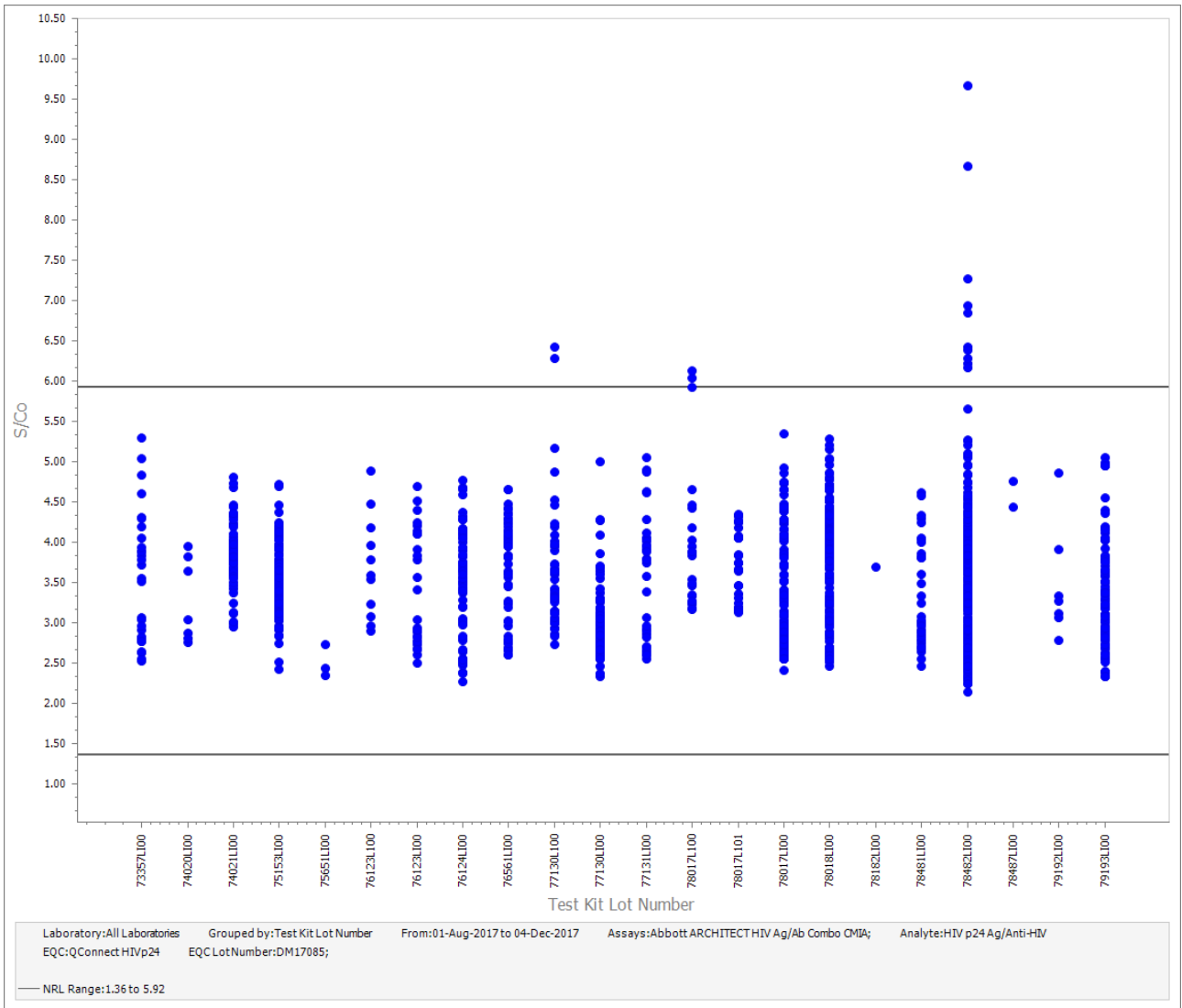


Figure 10

Table 1

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
8	138	3.98	0.43	3.12	4.85	2.94	4.86	10.90
17	14	3.92	0.38	3.16	4.68	3.25	4.44	9.68
30	4	3.77	NA	NA	NA	2.79	4.76	NA
36	45	2.87	0.41	2.05	3.70	2.47	5.00	14.34
40	41	3.27	0.69	1.90	4.64	2.34	4.75	20.93
43	146	3.71	1.16	1.38	6.03	2.25	9.67	31.34
49	20	3.29	0.46	2.36	4.22	2.84	4.41	14.09
50	115	4.04	0.29	3.46	4.61	3.08	4.66	7.16
58	79	3.57	0.49	2.59	4.55	2.74	4.89	13.71
64	155	3.53	0.40	2.74	4.32	2.42	4.72	11.20
66	94	3.12	0.54	2.04	4.19	2.35	4.66	17.30
123	13	3.95	0.52	2.90	5.00	3.38	4.97	13.27
128	47	3.03	0.70	1.63	4.42	2.15	4.75	23.00
129	74	3.46	0.77	1.92	5.01	2.43	5.21	22.29
145	149	3.68	0.75	2.18	5.19	2.27	5.66	20.45
169	32	3.90	0.55	2.80	5.00	3.01	5.04	14.05
176	28	3.89	0.57	2.76	5.03	2.67	4.93	14.60
180	66	3.00	0.45	2.11	3.90	2.46	4.62	14.88
183	26	3.39	0.78	1.83	4.94	2.63	5.35	22.96
378	1	3.30	NA	NA	NA	3.30	3.30	NA
884	1	3.57	NA	NA	NA	3.57	3.57	NA
938	38	3.97	1.05	1.87	6.07	2.76	6.42	26.40
1015	52	3.68	0.75	2.18	5.18	2.53	5.30	20.33
Totals	1378	3.59	0.74	2.10	5.07	2.15	9.67	20.69

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: DM17085

Table 2

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
8	266	5.49	0.40	4.69	6.29	4.47	6.47	7.28
9	182	5.60	0.40	4.80	6.40	3.94	6.69	7.15
12	33	4.43	0.63	3.17	5.68	2.94	5.51	14.15
17	360	5.44	0.49	4.46	6.43	2.72	8.60	9.06
30	666	4.73	0.69	3.36	6.10	2.26	10.75	14.50
32	172	5.68	0.35	4.99	6.37	2.93	6.72	6.07
36	341	5.47	0.44	4.59	6.34	4.46	6.81	7.98
39	47	5.11	0.57	3.98	6.24	3.99	7.91	11.06
40	201	5.00	0.49	4.02	5.98	3.24	6.91	9.83
43	369	4.74	0.50	3.74	5.75	3.63	6.04	10.61
49	433	4.96	1.25	2.45	7.47	2.13	6.80	25.27
50	141	5.39	0.28	4.83	5.95	4.63	5.92	5.21
58	187	5.49	0.21	5.07	5.91	4.97	6.15	3.81
64	92	2.61	0.41	1.80	3.42	2.06	3.74	15.57
66	1	3.05	NA	NA	NA	3.05	3.05	NA
123	192	5.77	0.54	4.69	6.84	3.35	8.04	9.31
128	456	5.00	0.39	4.22	5.78	2.40	5.91	7.80
129	324	5.53	0.38	4.78	6.28	4.42	6.33	6.80
145	135	5.47	0.35	4.78	6.16	4.73	6.14	6.31
148	525	5.16	0.58	4.00	6.31	2.65	6.52	11.21
166	58	5.64	0.39	4.86	6.42	4.92	6.27	6.90
169	220	4.97	0.95	3.07	6.87	3.07	6.75	19.11
180	152	5.39	0.51	4.37	6.42	3.17	6.88	9.49
191	35	5.03	0.31	4.41	5.65	4.25	5.72	6.16
777	1	5.76	NA	NA	NA	5.76	5.76	NA
884	1	4.40	NA	NA	NA	4.40	4.40	NA
938	126	5.19	0.53	4.13	6.25	2.72	7.01	10.23
1015	214	5.59	0.34	4.91	6.28	4.24	6.56	6.13
Totals	5930	5.17	0.75	3.67	6.67	2.06	10.75	14.53

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 158876

Table 3

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
8	195	3.45	0.17	3.11	3.78	2.96	3.88	4.88
9	126	3.78	0.26	3.27	4.30	3.04	4.44	6.82
17	1	5.04	NA	NA	NA	5.04	5.04	NA
35	26	5.19	0.20	4.79	5.59	4.84	5.51	3.82
36	126	3.43	0.27	2.90	3.97	2.90	4.39	7.78
49	52	3.12	0.27	2.59	3.65	2.48	3.58	8.51
50	205	3.57	0.33	2.91	4.22	2.77	4.18	9.14
58	202	3.69	0.29	3.12	4.26	2.90	4.28	7.73
64	270	3.57	0.32	2.94	4.20	2.38	4.99	8.82
66	324	3.22	0.34	2.55	3.89	2.40	3.97	10.42
123	169	3.63	0.38	2.87	4.40	2.39	4.60	10.54
128	2	5.01	NA	NA	NA	4.31	5.70	NA
129	190	3.76	0.22	3.31	4.21	3.31	4.83	5.96
145	195	3.59	0.20	3.20	3.99	3.11	4.10	5.51
169	105	3.84	0.25	3.35	4.34	3.19	4.63	6.40
176	140	3.16	0.46	2.25	4.08	2.14	4.09	14.45
180	170	3.87	0.29	3.30	4.44	3.10	5.12	7.37
290	1	4.83	NA	NA	NA	4.83	4.83	NA
371	1	4.34	NA	NA	NA	4.34	4.34	NA
377	2	4.67	NA	NA	NA	4.66	4.67	NA
382	1	4.04	NA	NA	NA	4.04	4.04	NA
1015	136	3.64	0.25	3.13	4.15	3.12	4.20	6.95
Totals	2639	3.57	0.40	2.77	4.38	2.14	5.70	11.26

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 160766

Table 4

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
17	335	4.40	0.39	3.61	5.19	2.91	5.33	8.95
39	34	3.77	0.95	1.87	5.68	2.98	8.60	25.23
43	239	4.00	0.49	3.02	4.98	2.78	5.92	12.27
58	168	3.84	0.28	3.28	4.40	3.09	4.39	7.27
64	604	4.23	0.36	3.52	4.95	3.32	6.12	8.48
129	184	4.14	0.42	3.29	4.98	3.21	5.73	10.18
138	1	4.75	NA	NA	NA	4.75	4.75	NA
169	150	4.01	0.54	2.93	5.09	3.10	5.63	13.44
180	152	3.93	0.35	3.23	4.64	3.18	5.54	9.00
183	156	3.97	0.56	2.85	5.09	3.09	6.44	14.14
191	30	3.99	0.39	3.20	4.77	3.38	4.71	9.86
884	1	3.96	NA	NA	NA	3.96	3.96	NA
Totals	2054	4.12	0.47	3.19	5.05	2.78	8.60	11.28

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 169561

Table 5

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
2	1	4.95	NA	NA	NA	4.95	4.95	NA
8	36	2.17	0.24	1.68	2.65	1.81	2.75	11.27
9	165	2.46	0.36	1.73	3.18	1.85	4.43	14.83
12	7	2.90	NA	NA	NA	2.09	3.24	NA
30	26	2.31	0.36	1.60	3.02	1.71	3.03	15.37
36	92	2.52	0.36	1.80	3.24	1.93	3.67	14.30
40	278	2.50	0.55	1.40	3.60	1.68	5.20	22.08
49	3	2.42	NA	NA	NA	2.41	2.43	NA
50	2	7.17	NA	NA	NA	7.11	7.23	NA
58	67	2.60	0.17	2.26	2.94	2.24	2.98	6.62
64	2	2.52	NA	NA	NA	2.33	2.70	NA
128	45	2.71	0.26	2.18	3.23	2.27	3.60	9.68
129	29	2.86	0.30	2.26	3.46	2.33	3.48	10.56
148	5	2.64	NA	NA	NA	2.44	2.88	NA
166	1	5.15	NA	NA	NA	5.15	5.15	NA
169	111	2.69	0.62	1.46	3.93	1.91	6.48	22.97
176	33	2.57	0.28	2.00	3.14	1.95	3.12	11.04
180	51	2.56	0.29	1.98	3.15	2.03	3.31	11.43
183	113	2.60	1.10	0.40	4.80	1.17	5.09	42.29
191	12	2.50	0.25	2.01	2.99	2.13	2.88	9.84
361	3	4.19	NA	NA	NA	3.76	4.42	NA
365	1	4.55	NA	NA	NA	4.55	4.55	NA
369	1	4.70	NA	NA	NA	4.70	4.70	NA
374	1	4.52	NA	NA	NA	4.52	4.52	NA
382	1	3.79	NA	NA	NA	3.79	3.79	NA
384	2	4.91	NA	NA	NA	4.72	5.10	NA
834	1	6.19	NA	NA	NA	6.19	6.19	NA
884	15	5.95	0.60	4.75	7.15	4.09	6.61	10.06
938	49	2.76	0.22	2.31	3.20	2.25	3.50	8.05
Totals	1153	2.63	0.73	1.17	4.08	1.17	7.23	27.76

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 334302

Table 6

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
2	1	3.99	NA	NA	NA	3.99	3.99	NA
9	104	2.21	0.35	1.52	2.90	1.63	3.84	15.62
12	13	2.16	0.38	1.40	2.93	1.73	2.81	17.72
17	219	2.52	0.34	1.83	3.20	1.81	3.38	13.55
25	1	5.03	NA	NA	NA	5.03	5.03	NA
32	94	2.16	0.47	1.22	3.10	1.75	4.90	21.69
36	172	1.81	0.25	1.31	2.32	1.41	2.64	13.97
43	125	2.38	0.36	1.67	3.09	1.77	4.55	14.92
46	2	4.50	NA	NA	NA	3.63	5.36	NA
49	256	2.03	0.37	1.28	2.77	1.36	4.46	18.36
50	203	2.57	0.29	1.98	3.16	2.06	4.70	11.40
58	196	2.35	0.25	1.85	2.85	1.83	3.12	10.61
64	125	2.28	0.66	0.96	3.59	1.16	4.30	28.87
66	410	2.02	0.43	1.16	2.88	1.21	3.51	21.30
123	111	2.54	0.21	2.12	2.96	1.90	3.06	8.26
128	117	2.62	0.38	1.86	3.38	2.01	4.82	14.49
129	187	2.23	0.39	1.45	3.01	1.49	3.34	17.50
145	209	2.22	0.43	1.36	3.08	1.59	3.62	19.38
148	190	2.60	0.42	1.77	3.44	1.58	4.70	16.10
166	1	2.74	NA	NA	NA	2.74	2.74	NA
176	64	2.15	0.50	1.15	3.15	1.43	4.86	23.35
180	164	2.11	0.39	1.34	2.88	1.62	4.75	18.29
191	88	2.57	0.64	1.29	3.85	1.56	4.90	24.96
368	1	3.74	NA	NA	NA	3.74	3.74	NA
371	1	4.61	NA	NA	NA	4.61	4.61	NA
374	1	4.30	NA	NA	NA	4.30	4.30	NA
375	1	4.19	NA	NA	NA	4.19	4.19	NA
376	1	4.53	NA	NA	NA	4.53	4.53	NA
938	194	2.55	0.52	1.52	3.58	1.55	3.72	20.20
Totals	3251	2.29	0.48	1.33	3.25	1.16	5.36	21.05

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 416805

Table 7

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
8	135	2.96	0.25	2.46	3.47	2.46	3.47	8.50
9	98	2.89	0.32	2.24	3.53	2.13	3.97	11.19
12	37	2.59	0.41	1.76	3.41	1.77	3.41	16.02
17	178	3.25	0.34	2.58	3.92	2.48	3.90	10.32
30	1010	2.77	0.47	1.83	3.71	1.91	7.71	16.94
32	176	2.74	0.49	1.76	3.72	2.16	6.92	17.91
36	186	2.60	0.24	2.13	3.07	2.10	4.08	9.05
39	51	2.30	0.22	1.86	2.74	1.82	3.01	9.56
40	555	2.73	0.35	2.03	3.42	1.93	4.24	12.70
43	363	2.91	0.33	2.25	3.56	2.14	5.23	11.24
50	213	2.95	0.16	2.64	3.26	2.46	3.44	5.29
58	359	2.96	0.27	2.42	3.50	2.28	4.25	9.16
64	267	2.73	0.58	1.56	3.89	1.65	5.22	21.31
66	350	2.56	0.33	1.91	3.21	1.97	3.90	12.69
123	104	3.06	0.56	1.94	4.18	1.57	3.68	18.24
128	261	3.01	0.22	2.56	3.46	2.34	4.10	7.44
129	176	3.01	0.39	2.23	3.79	2.32	4.55	12.98
145	167	2.93	0.20	2.52	3.33	2.36	3.41	6.87
166	167	3.10	0.35	2.41	3.80	2.44	4.07	11.19
169	207	2.99	0.36	2.27	3.71	2.22	3.87	12.04
176	121	2.64	0.41	1.82	3.46	1.65	3.52	15.49
180	181	2.74	0.33	2.08	3.41	2.04	4.81	12.14
183	80	2.94	0.63	1.69	4.19	2.21	4.77	21.31
191	102	2.85	0.21	2.42	3.28	2.31	3.27	7.50
290	22	3.13	0.45	2.24	4.03	2.61	4.29	14.23
938	105	2.95	0.33	2.30	3.60	2.40	3.98	11.05
1015	16	2.96	0.31	2.34	3.57	2.50	3.43	10.42
Totals	5687	2.84	0.41	2.02	3.66	1.57	7.71	14.48

Legend:

Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2014 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: 425806

Table 8

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
73357LI00	29	3.56	0.81	1.94	5.17	2.53	5.30	22.67
74020LI00	7	3.27	NA	NA	NA	2.76	3.95	NA
74021LI00	65	3.87	0.40	3.07	4.67	2.95	4.81	10.35
75153LI00	154	3.52	0.39	2.74	4.30	2.42	4.72	11.14
75651LI00	3	2.51	NA	NA	NA	2.35	2.74	NA
76123L100	11	3.69	0.64	2.40	4.98	2.90	4.89	17.45
76123LI00	27	3.41	0.71	2.00	4.82	2.50	4.69	20.69
76124LI00	60	3.51	0.67	2.18	4.84	2.27	4.77	18.96
76561LI00	60	3.69	0.60	2.49	4.89	2.60	4.66	16.28
77130L100	52	3.62	0.76	2.09	5.14	2.74	6.42	21.07
77130LI00	79	3.01	0.45	2.10	3.91	2.34	5.00	15.07
77131LI00	33	3.59	0.77	2.06	5.12	2.56	5.05	21.30
78017L100	22	4.03	0.93	2.18	5.88	3.17	6.13	22.94
78017L101	26	3.66	0.43	2.79	4.52	3.13	4.35	11.79
78017LI00	110	3.42	0.70	2.01	4.83	2.41	5.35	20.60
78018LI00	195	3.84	0.65	2.55	5.14	2.47	5.29	16.83
78182LI00	1	3.70	NA	NA	NA	3.70	3.70	NA
78481LI00	35	3.33	0.64	2.05	4.62	2.46	4.62	19.32
78482LI00	236	3.61	1.07	1.47	5.74	2.15	9.67	29.56
78487LI00	2	4.60	NA	NA	NA	4.44	4.76	NA
79192LI00	7	3.48	NA	NA	NA	2.79	4.86	NA
79193LI00	88	3.38	0.64	2.09	4.66	2.33	5.05	18.99
Totals	1302	3.57	0.75	2.07	5.07	2.15	9.67	20.96

Legend:

Laboratory: All Laboratories
 Grouped by: Test Kit Lot Number
 From: 01-Aug-2017 to 04-Dec-2017
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo
 Analyte: HIV p24 Ag/Anti-HIV
 EQC: QConnect HIVp24
 EQC Lot Number: DM17085