QC INVESTIGATIONS

Investigation of QConnect Blue (424521) reactivity in the Abbott ARCHITECT HCV assay.

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QConnect
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Report prepared by Marina Karakaltsas

authorised by Liza Cabuang

and distributed in the week beginning 2015-11-23

1 Introduction

Participant 176 contacted NRL about the HCV reactivity of QConnect Blue (424521) tested in the Abbott ARCHITECT HCV assay. They observed results for QConnect Blue (424521) below 2.0 S/Co and stated that QConnect limits set by NRL for the Abbott ARCHITECT HCV assay were between 2.0 to 3.0 S/Co.

The limits in QConnect EDCNet for all three QConnect Blue lots (402302, 413301 and 424521) are 1.7 - 2.9 S/Co. These limits were recently changed (approximately October 2015). The limits for the Abbott ARCHITECT HCV were previously from 1.9 to 2.9 S/Co.

2 Findings

Figure 1 shows a scatter plot of the data submitted to QConnect EDCNet for QConnect Blue (424521) tested in the Abbott ARCHITECT HCV assay between 01/01/2015 to 19/11/2015, by participant. The NRL QConnect limits from 1.7 to 2.9 S/Co are also shown. This scatter plot shows there are many results below 2.0 S/Co and fewer results below 1.7 S/Co. Most of the results from Participants 359 to 384 were between 1.7 and 2.9 S/Co.

Figure 2 shows the mean ± 2SD of the data submitted to QConnect EDCNet for QConnect Blue (424521) tested in the Abbott ARCHITECT HCV assay between 01/01/2015 to 19/11/2015, by reagent lot with NRL QConnect limits from 1.7 to 2.9 S/Co also shown. From this chart it appears that the change in reactivity of QConnect Blue (424521) coincided with changes in kit reagent lots.

It appears that the mean reactivity of QConnect Blue (424521) has decreased for reagent lots between 48294LI00 and 53126LI00 when compared with reagent lot reactivity before and after these reagent lots in Figure 2.

In Table 1, any reagent lots with a mean of ≤ 2.19 S/Co have been highlighted. Most of the reagent lots highlighted coincide with the decreased mean reactivity of QConnect Blue for reagent lots between 48294LI00 and 53126LI00 as shown in Figure 2.

As participant 176 does not appear to have submitted data, Figures 3 and 4 show Participant 884's results by reagent lot as a random representative data set. Figure 3 shows a scatter plot of their data and Figure 4 shows the mean ± 2SD of their data. From these two figures it appears that the reactivity of QConnect Blue (424521) has changed with changes in kit reagent lots.

3 Conclusion

Testing QConnect Blue (424521) in the Abbott ARCHITECT HCV assay showed that the ARCHITECT HCV reagent lot reactivity changed over time. The mean of results for reagent lots between approximately 48294LI00 and 53126LI00 appear to be lower than the reactivity observed for reagent lots before 48294LI00 and after reagent lot 53126LI00. Reactivity for reagent lots before 48294LI00 and after reagent lot 53126LI00 appeared to be similar. There are many factors that can lead to changes in reagent lot reactivity such as sources of "new" material used to make the reagent lots.

Abbott Laboratories confirmed that the shift in reagent lot results did not affect patient results.

4 Recommendations

NRL recommends that participants use the NRL control limits as a guide. NRL recommends that Participant 176 submit their data to EDCNet where they will be able to compare their data with the peer group and find the most up to date limits.

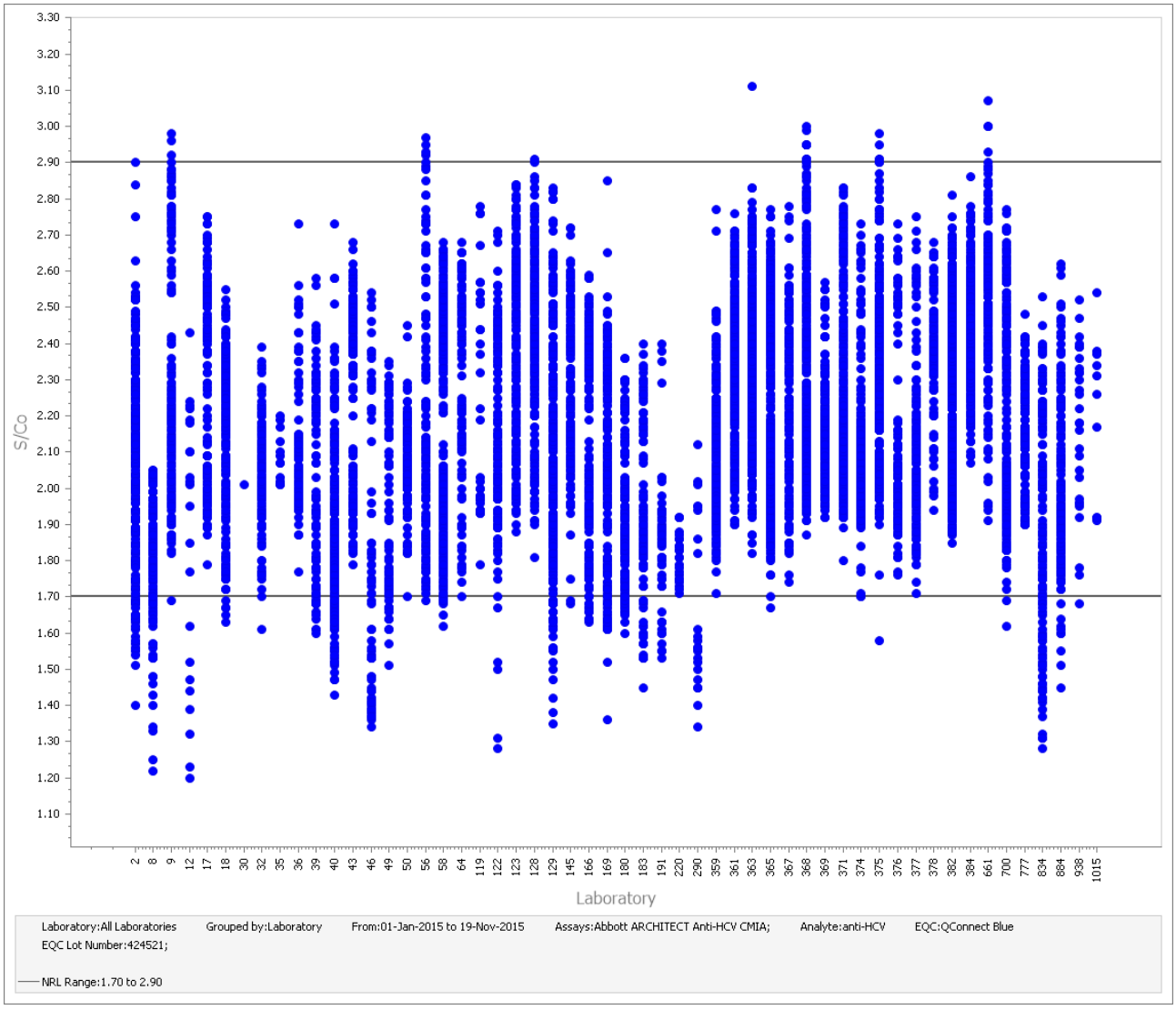


Figure 1

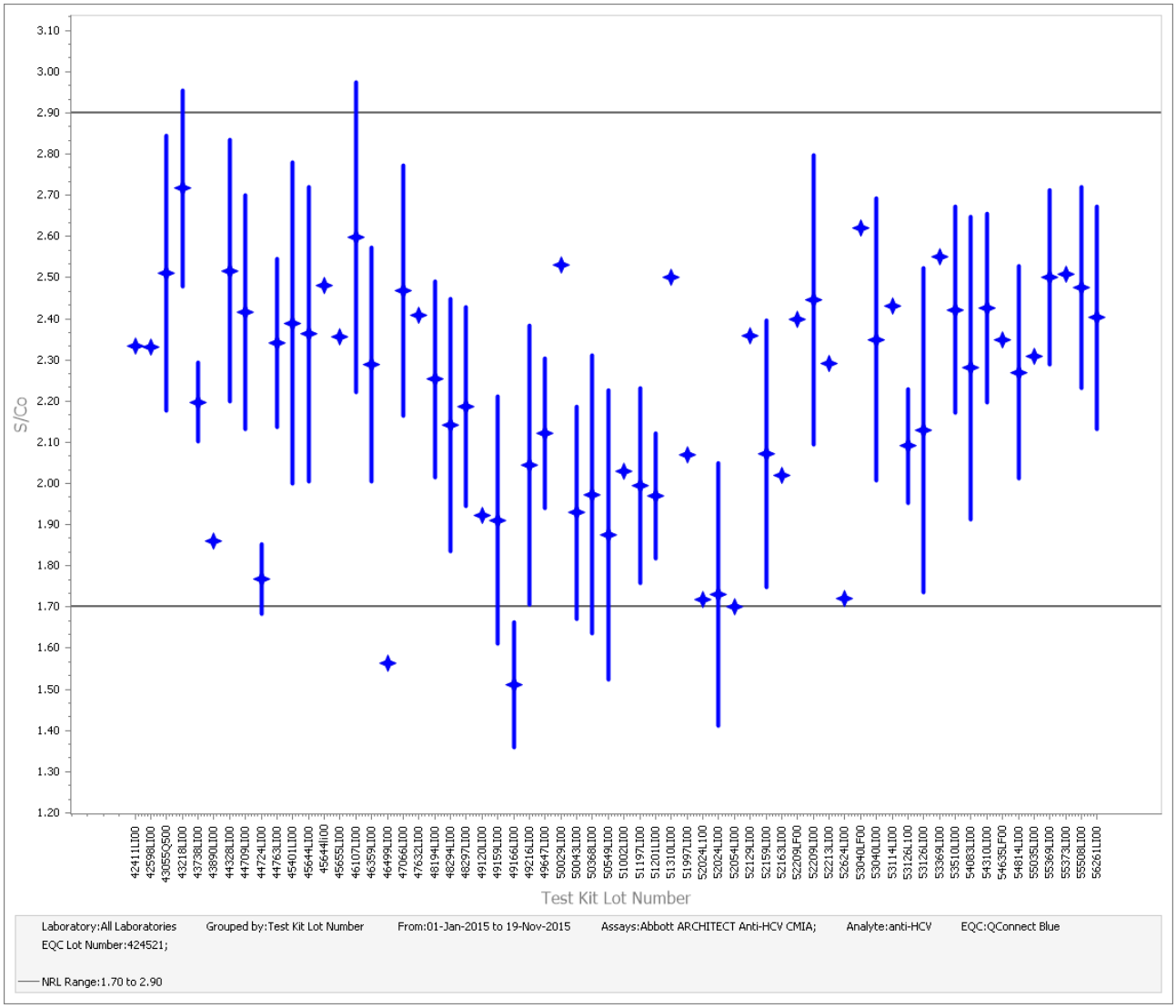
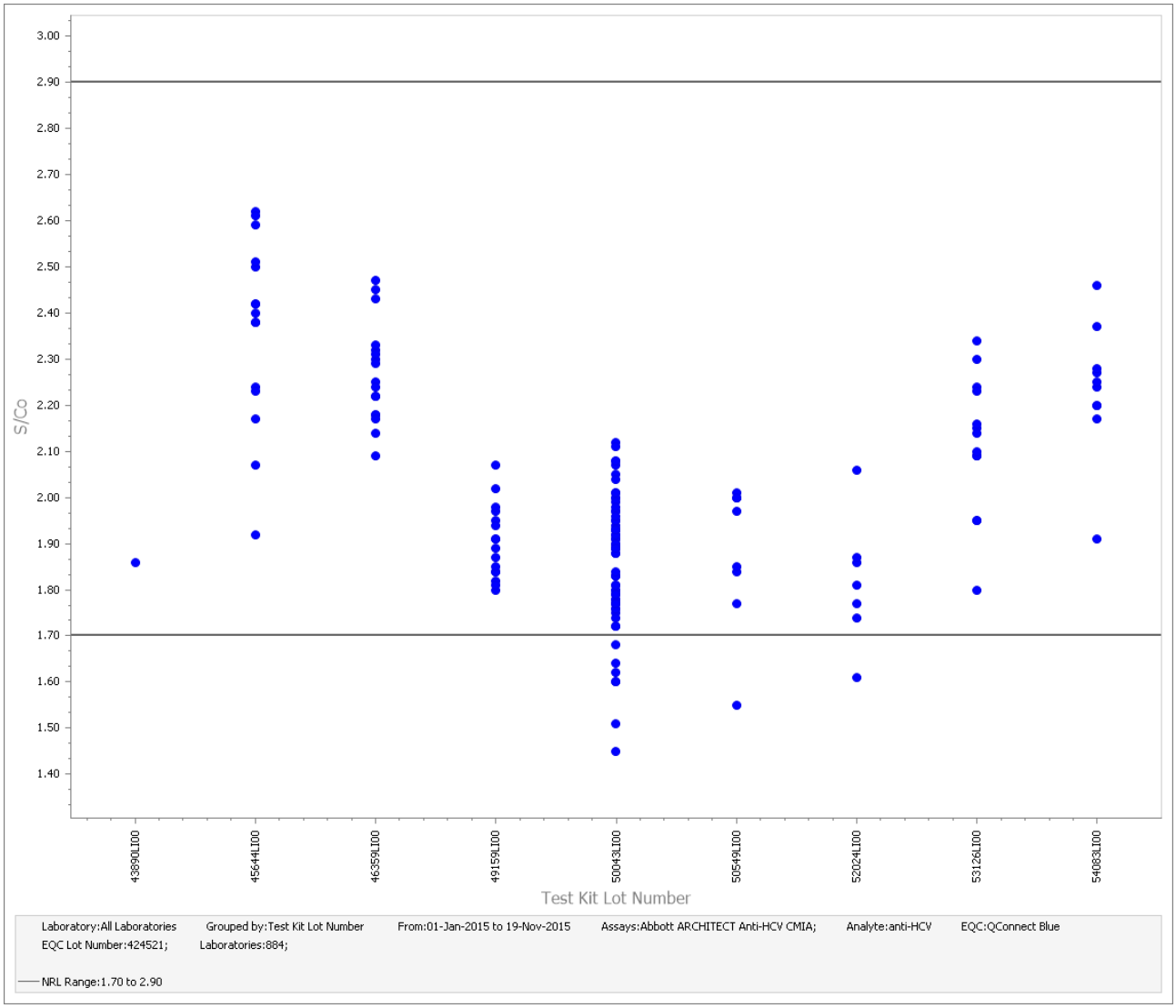

S/Co
Test Kit Lot Number
Laboratory:All Laboratories
Grouped by:Test Kit Lot Number
From:01-Jan-2015 to 19-Nov-2015
Assays:Abbott ARCHITECT Anti-HCV CMIA;
Analyte:anti-HCV
EQC:QConnect Blue
EQC Lot Number:424521;
NRL Range:1.70 to 2.90

Figure 2

Table 1: QConnect Blue (424521) tested in the Abbott ARCHITECT Anti-HCV CMIA between 01/01/2015 and 19/11/2015 by reagent lot.

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
42411LI00	7	2.33	NA	NA	NA	2.15	2.46	NA
42598LI00	4	2.33	NA	NA	NA	2.24	2.41	NA
43055Q500	61	2.51	0.17	2.18	2.85	2.02	2.87	6.65
43218LI00	19	2.72	0.12	2.48	2.96	2.54	2.98	4.38
43738LI00	10	2.20	0.05	2.10	2.29	2.14	2.28	2.18
43890LI00	1	1.86	NA	NA	NA	1.86	1.86	NA
44328LI00	205	2.52	0.16	2.20	2.84	2.13	2.96	6.32
44709LI00	51	2.42	0.14	2.13	2.70	2.01	2.68	5.88
44724LI00	10	1.77	0.04	1.68	1.85	1.68	1.83	2.38
44763LI00	111	2.34	0.10	2.14	2.55	2.01	2.56	4.36
45401LI00	219	2.39	0.20	2.00	2.78	1.58	2.98	8.16
45644LI00	364	2.36	0.18	2.00	2.72	1.82	2.90	7.61
45655LI00	3	2.36	NA	NA	NA	2.29	2.40	NA
46107LI00	291	2.60	0.19	2.22	2.98	2.14	3.11	7.23
46359LI00	164	2.29	0.14	2.01	2.57	1.88	2.53	6.20
46499LI00	9	1.56	NA	NA	NA	1.20	1.92	NA
47066LI00	588	2.47	0.15	2.17	2.77	1.89	2.95	6.16
47632LI00	1	2.41	NA	NA	NA	2.41	2.41	NA
48194LI00	91	2.25	0.12	2.02	2.49	2.00	2.53	5.28
48294LI00	929	2.14	0.15	1.84	2.45	1.40	2.77	7.14
48297LI00	82	2.19	0.12	1.94	2.43	1.82	2.74	5.54
49120LI00	5	1.92	NA	NA	NA	1.69	2.05	NA
49159LI00	244	1.91	0.15	1.61	2.21	1.28	2.31	7.85
49166LI00	15	1.51	0.08	1.36	1.66	1.34	1.61	5.03
49216LI00	607	2.05	0.17	1.71	2.39	1.56	2.62	8.31
49647LI00	10	2.12	0.09	1.94	2.31	1.98	2.27	4.29
50029LI00	1	2.53	NA	NA	NA	2.53	2.53	NA
50043LI00	464	1.93	0.13	1.67	2.19	1.39	2.85	6.68
50368LI00	474	1.97	0.17	1.64	2.31	1.22	2.78	8.57
50549LI00	264	1.88	0.18	1.52	2.23	1.36	2.27	9.39
51002LI00	1	2.03	NA	NA	NA	2.03	2.03	NA
51197LI00	218	2.00	0.12	1.76	2.23	1.70	2.26	5.96
51201LI00	12	1.97	0.08	1.82	2.12	1.87	2.11	3.86
51310LI00	1	2.50	NA	NA	NA	2.50	2.50	NA
51997LI00	1	2.07	NA	NA	NA	2.07	2.07	NA
52024L100	6	1.72	NA	NA	NA	1.55	1.91	NA
52024LI00	456	1.73	0.16	1.41	2.05	1.34	2.44	9.24
52054LI00	3	1.70	NA	NA	NA	1.68	1.73	NA
52129LI00	1	2.36	NA	NA	NA	2.36	2.36	NA
52159LI00	1189	2.07	0.16	1.75	2.40	1.70	2.90	7.81
52163LI00	4	2.02	NA	NA	NA	1.98	2.05	NA
52209LI00	620	2.45	0.18	2.09	2.80	1.78	3.07	7.20
52213LI00	9	2.29	NA	NA	NA	2.06	2.45	NA

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
52624LI00	1	1.72	NA	NA	NA	1.72	1.72	NA
53040LI00	218	2.35	0.17	2.01	2.70	1.84	2.85	7.32
53114LI00	1	2.43	NA	NA	NA	2.43	2.43	NA
53126L100	12	2.09	0.07	1.95	2.23	2.01	2.20	3.30
53126LI00	324	2.13	0.20	1.74	2.52	1.45	2.84	9.25
53369LI00	2	2.50	NA	NA	NA	2.45	2.55	NA
53510LI00	310	2.42	0.13	2.17	2.67	2.10	2.84	5.16
54083LI00	209	2.28	0.18	1.91	2.65	1.74	2.66	8.07
54310LI00	293	2.43	0.12	2.20	2.66	2.12	2.75	4.74
54635LI00	1	2.35	NA	NA	NA	2.35	2.35	NA
54814LI00	36	2.27	0.13	2.01	2.53	1.94	2.52	5.68
55035LI00	5	2.31	NA	NA	NA	1.98	2.46	NA
55369LI00	163	2.50	0.11	2.29	2.71	2.25	2.77	4.24
55373LI00	8	2.51	NA	NA	NA	2.05	2.72	NA
55508LI00	97	2.48	0.12	2.23	2.72	2.23	2.75	4.93
56261LI00	11	2.40	0.14	2.13	2.67	2.13	2.55	5.62
Totals	**9,516**	**2.19**	**0.28**	**1.63**	**2.76**	**1.20**	**3.11**	**12.81**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Test Kit Lot Number
Laboratory:All Laboratories
Grouped by:Test Kit Lot Number
From:01-Jan-2015 to 19-Nov-2015
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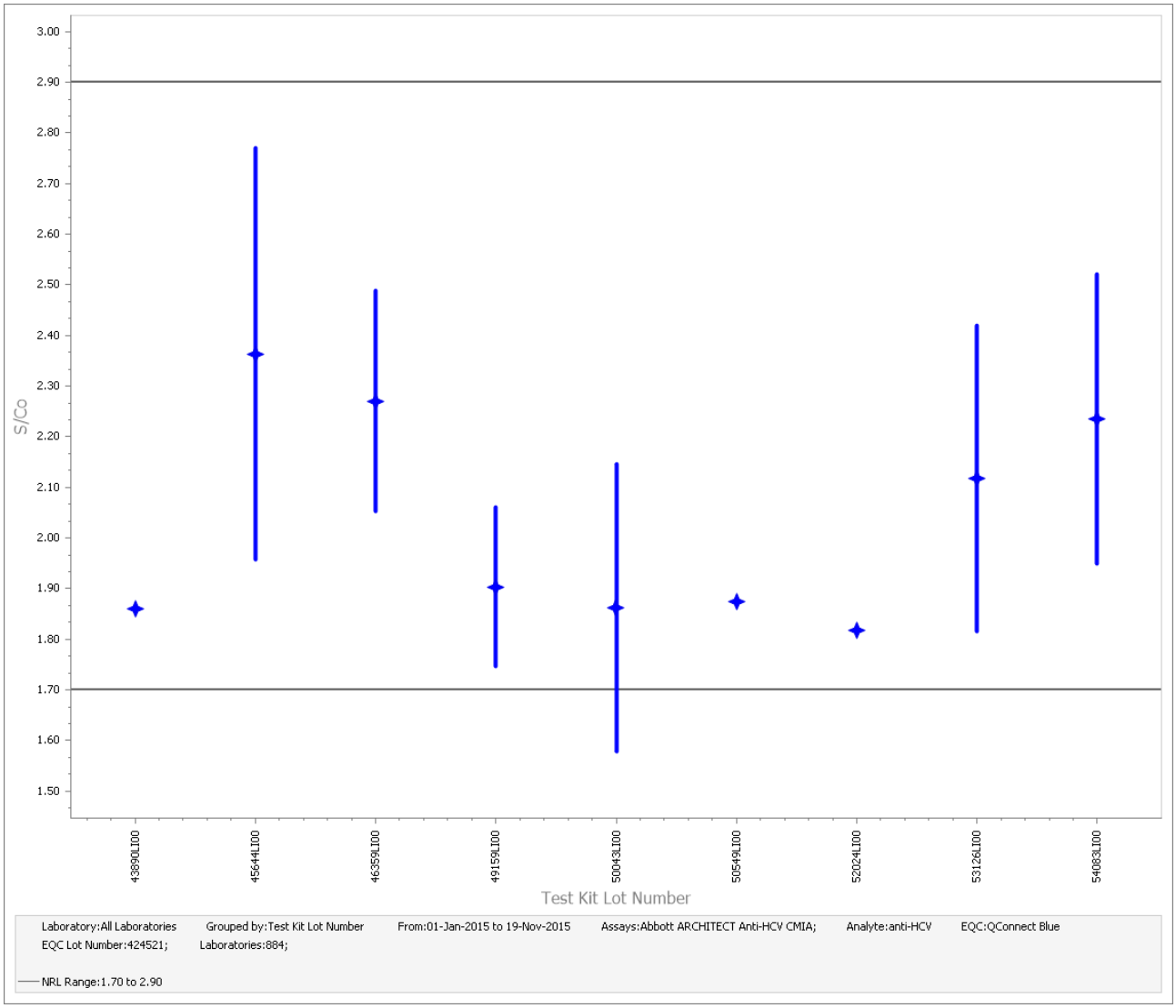
EQC:QConnect Blue
EQC Lot Number:424521;
Laboratories:884;
NRL Range:1.70 to 2.90

Figure 3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EQC:QConnect Blue
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Laboratories:884;
NRL Range:1.70 to 2.90

Figure 4

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