



# **QC SEROLOGY INVESTIGATION PMM-QC-706**

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- Certified by BSI for Safety Management, as compliant with AS/NZS 4801;
- A World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.

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**Date: 21/11/2019**



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## 1 Introduction

During routine review of EDCNet it was observed for the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect Blue DM18210, Participant 39 data was above the upper limit and not in line with peer group data.

## 2 Findings

Figure 1: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210.

Figure 2: Participant 39 data (red) in comparison with peer group for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by participant.

Figure 3: Participant 39 data (red) in comparison with peer group for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by reagent lot.

Figure 4: Participant 39 data and comments for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue:DM18210.

Figure 5: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Negative Kit Control.

Figure 6: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 1 Kit Control.

Figure 7: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 2 Kit Control.

Figure 8: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 3 (Viral Lysate) Kit Control.

Figure 9: Participant 39 data (red) in comparison with peer group Abbott ARCHITECT HBsAg Qualitative II, QConnect Blue:DM18210 by participant.

Figure 10: Participant 39 data (red) in comparison with peer group Abbott ARCHITECT Anti-HCV, QConnect Blue:DM18210 by participant.

Table 1: Participant 39 raw data for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by reagent lot.

Table 2: Participant 39 data (red) in comparison with peer group for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by participant.

### 3 Discussion

When investigating Participant 39 out of range data for the Abbott ARCHITECT HIV Ag/Ab Combo, HIVp24/Anti-HIV assay testing with QConnect Blue DM18210, data from all available QC material, both EQC and kit controls from all participants in the peer group were investigated to establish whether there was any evidence of trends or patterns across the peer group or QC materials.

Figure one shows Participant 39 data for the Abbott ARCHITECT HIV Ag/Ab Combo, HIVp24/Anti-HIV assay testing with QConnect Blue DM18210 from the 21st August 2019 until 14<sup>th</sup> November 2019. Three reagent lots were in use, 03257BE00, 04485BE00 and 06093BE00. The majority of data was entered under the two latter lots (04485BE00 and 06093BE00) and 75% of that data was above the NRL Range of S/Co 6.20 (Table 1).

As can be seen in figures two and three, participant 39 data was above peer group data for all reagent lots in use (Figure 2) and more specifically for the three reagent lots mentioned above (Figure 3). This is further illustrated in Table 2, where the mean of participant 39 (S/Co 6.54) was above both the individual mean for all other participants which ranged from S/Co 2.96 to 5.44 and the total peer group mean of S/Co 4.49.

Participant 39 did not originally supply kit control data in EDCNet for comparison and analysis. NRL requested, received and entered the relevant kit control data from participant 39 (Figures 7, 8, 9 & 10). Figures 8, 9 and 10 (Positive 1, Positive 2 and Positive 3 (Viral Lysate) Kit controls respectively) illustrate the positive kit controls show the same shift up in data seen in QConnect Blue:DM18210.

The elevated reactivity was isolated to the Abbott ARCHITECT HIVAg/Ab Combo, HIVp24/Anti-HIV assay with neither the Abbott ARCHITECT HBsAg Qualitative II or Abbott ARCHITECT Anti-HCV testing with QConnect Blue:DM18210 exhibiting the same variation in data (Figures 9 and 10).

This variation of elevated data for the Abbott ARCHITECT HIV Ag/Ab Combo, HIVp24/Anti-HIV assay; QConnect Blue DM18210 was only identified for Participant 39. It was isolated to the Abbott ARCHITECT HIVAg/Ab Combo assay and not seen on other assays testing with the QConnect Blue DM18210. It was also identified in the positive kit

controls (POS1, POS2 and POS3 (viral lysate)), these factors indicate the cause of variation was Laboratory specific.

A possible cause of this variation was calibration lots used by Participant 39, this was investigated further. NRL obtained the calibrator lot numbers used by participant 39 (Table 3). Participant 39 did a total of five calibrations during the time period showing elevated data. The first four of these calibrations were done with calibrator lot 02130BE00 and the last was done with calibrator lot 04123BE00. The first four calibrations showed no change in the data values however the last calibration resulted in a drop in the S/Co value (Figure 4). After some investigation by NRL it was mentioned anecdotally by participant 39 that the two different calibrator lots were delivered to the laboratory in two separate shipments, suggesting that calibration lot 02130BE00 may have been damaged or corrupted during transport. It is likely that this is the cause of the variation observed.

## 4 Recommendations

NRL recommends participant 39 continue monitoring the Abbott ARCHITECT HIV Ag/Ab Combo assay to identify if the new calibration lot continues to result in S/Co values within range.

NRL recommends participant 39 implements a monitoring system for items during shipment. This system should ideally monitor ambient and internal temperature, light, tilt, pressure, physical shock during all stages of transport.

NRL recommends Participant 39 submit kit control data into EDCNet, allowing for more complete investigations.

NRL recommends participants review their EDCNet data frequently and compare their data to the peer group for accuracy and precision using all the chart functions available in EDCNet by participant and reagent lot number.

NRL recommends participants experiencing aberrant QC results, shifts in data or who have any queries about QConnect contact NRL for detailed investigations by contacting [qconnect@nrlquality.org.au](mailto:qconnect@nrlquality.org.au).

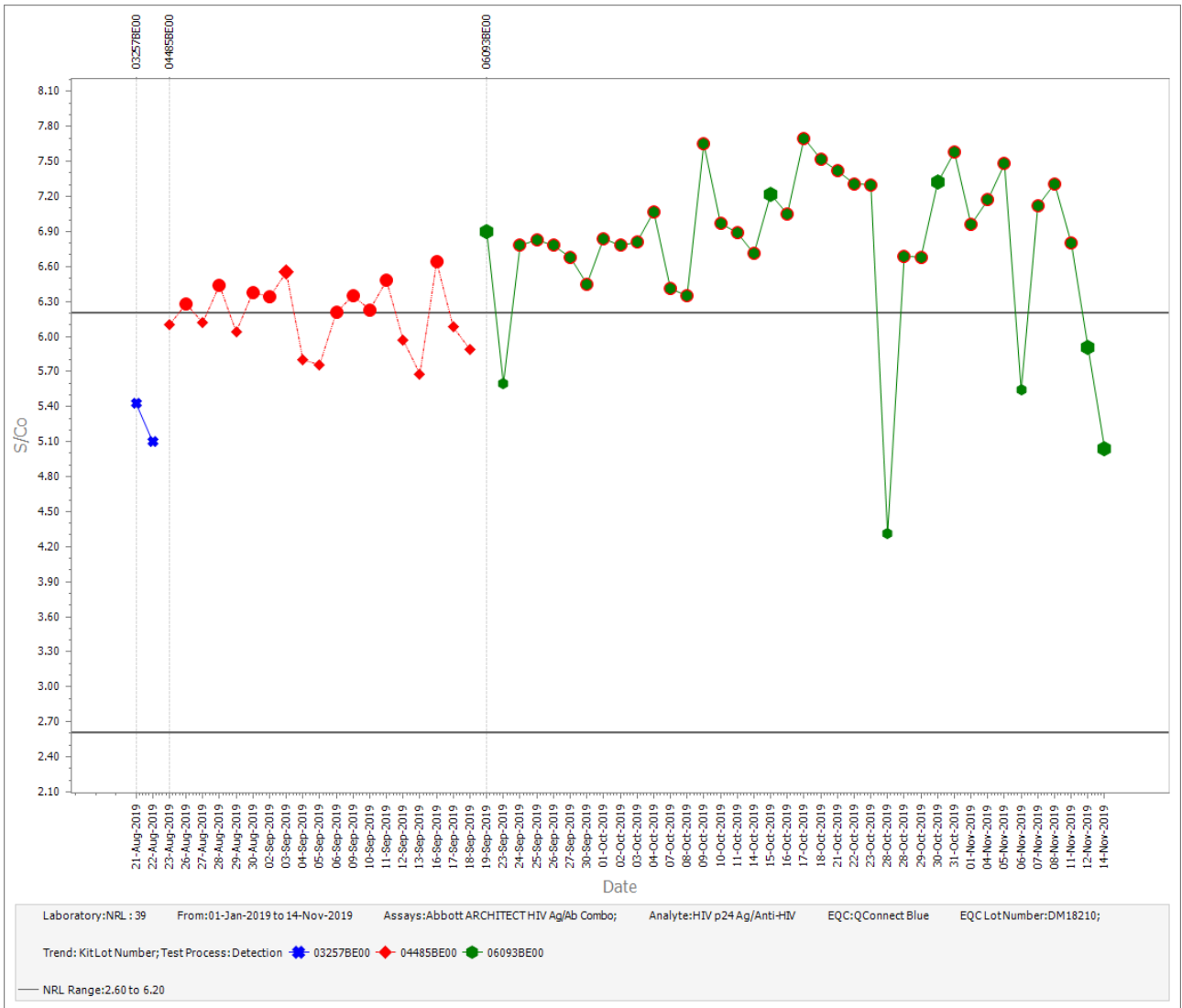


Figure 5: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue:DM18210.

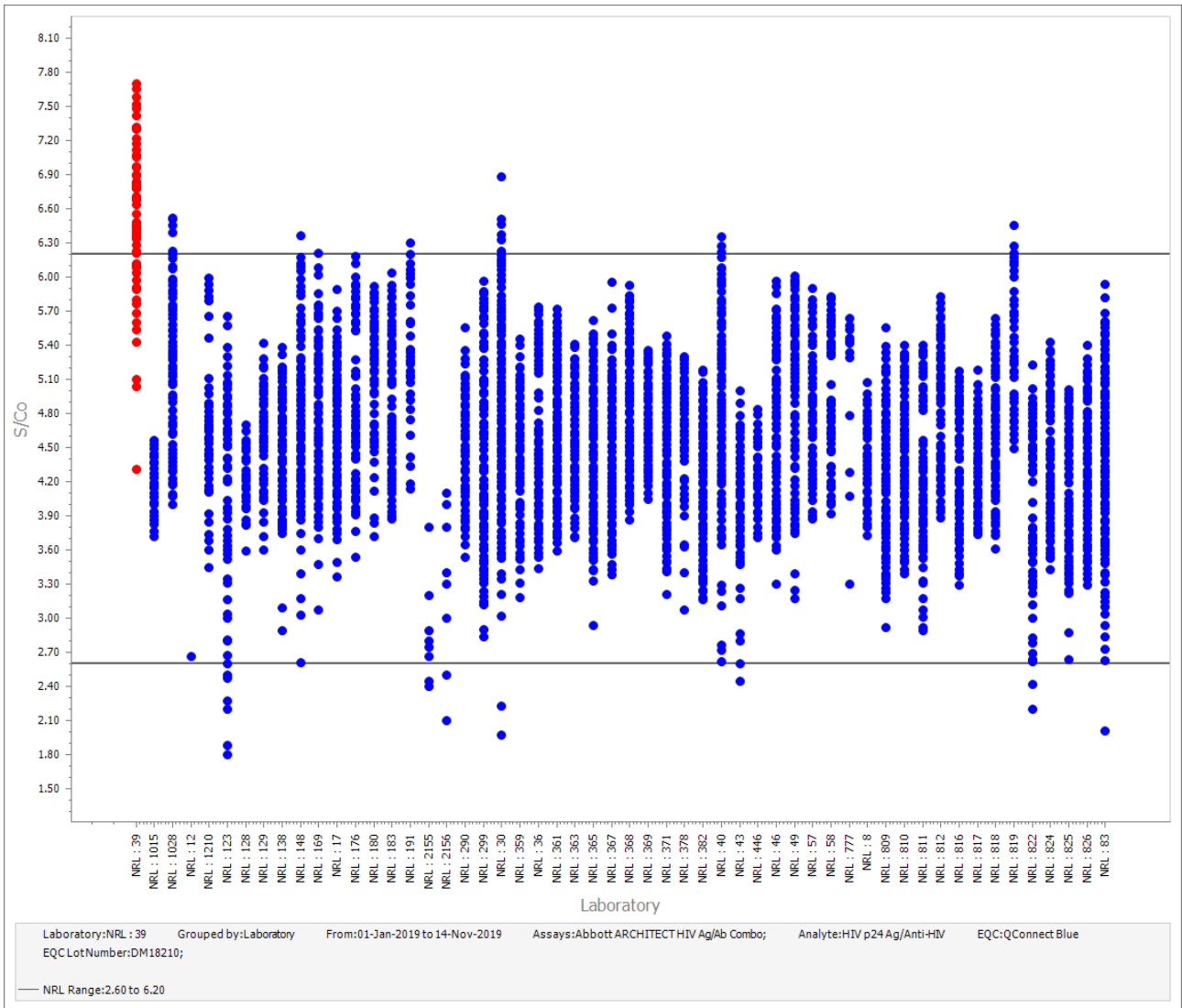


Figure 6: Participant 39 data (red) in comparison with peer group for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by participant.

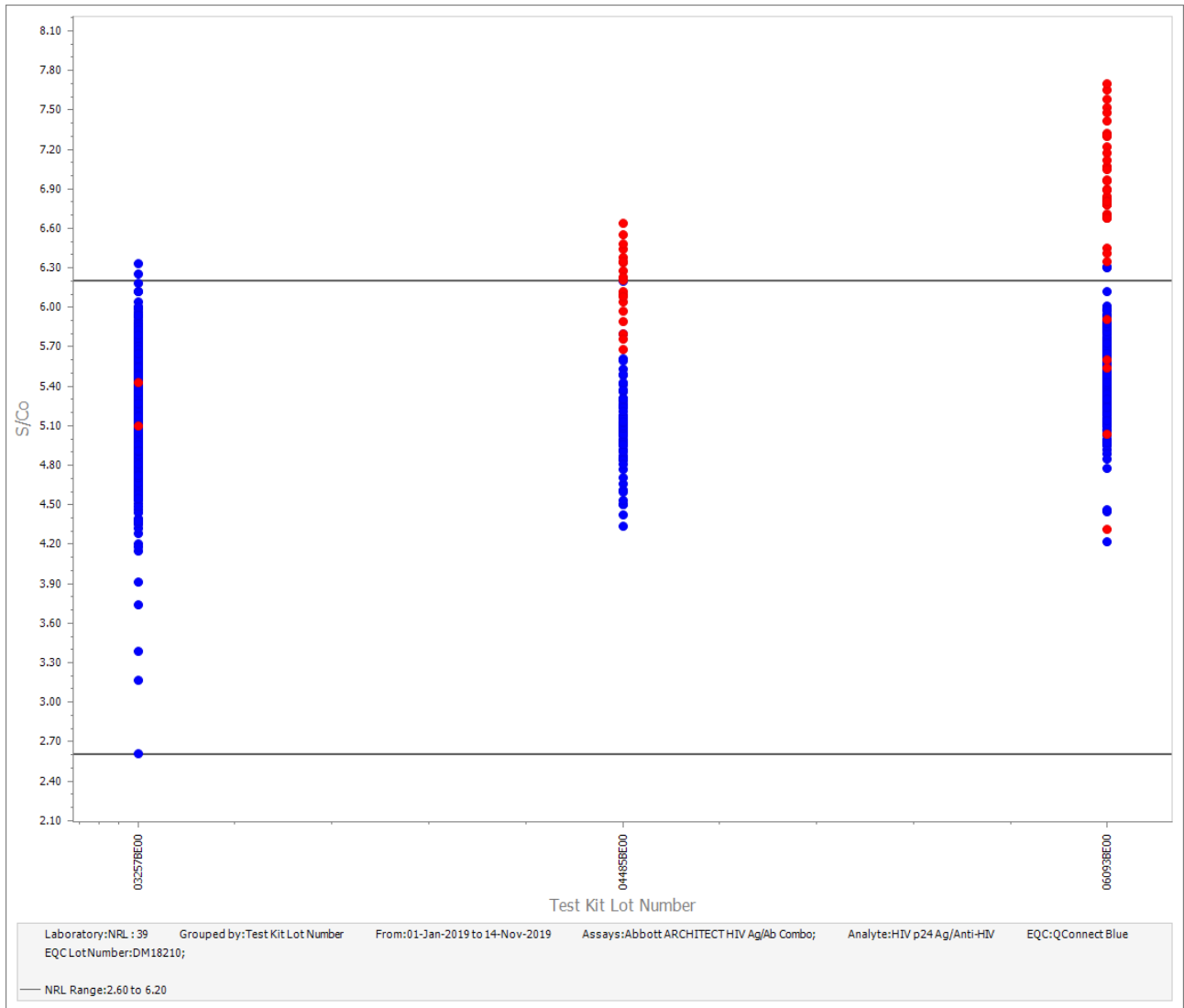


Figure 7: Participant 39 data (red) in comparison with peer group for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue: DM18210 by reagent lot.



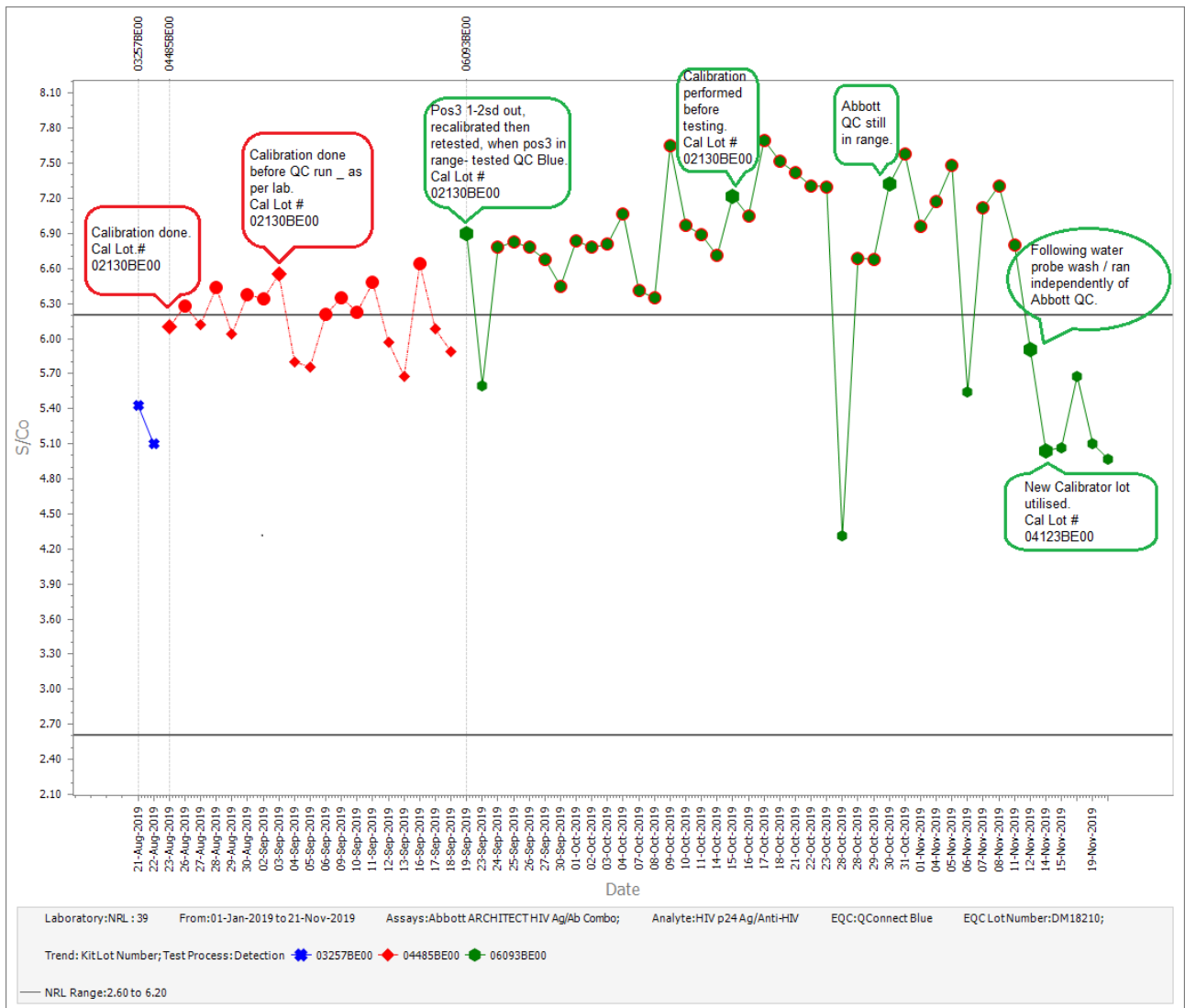


Figure 8: Participant 39 data and comments for Abbott ARCHITECT HIV Ag/Ab Combo, QConnect Blue:DM18210.

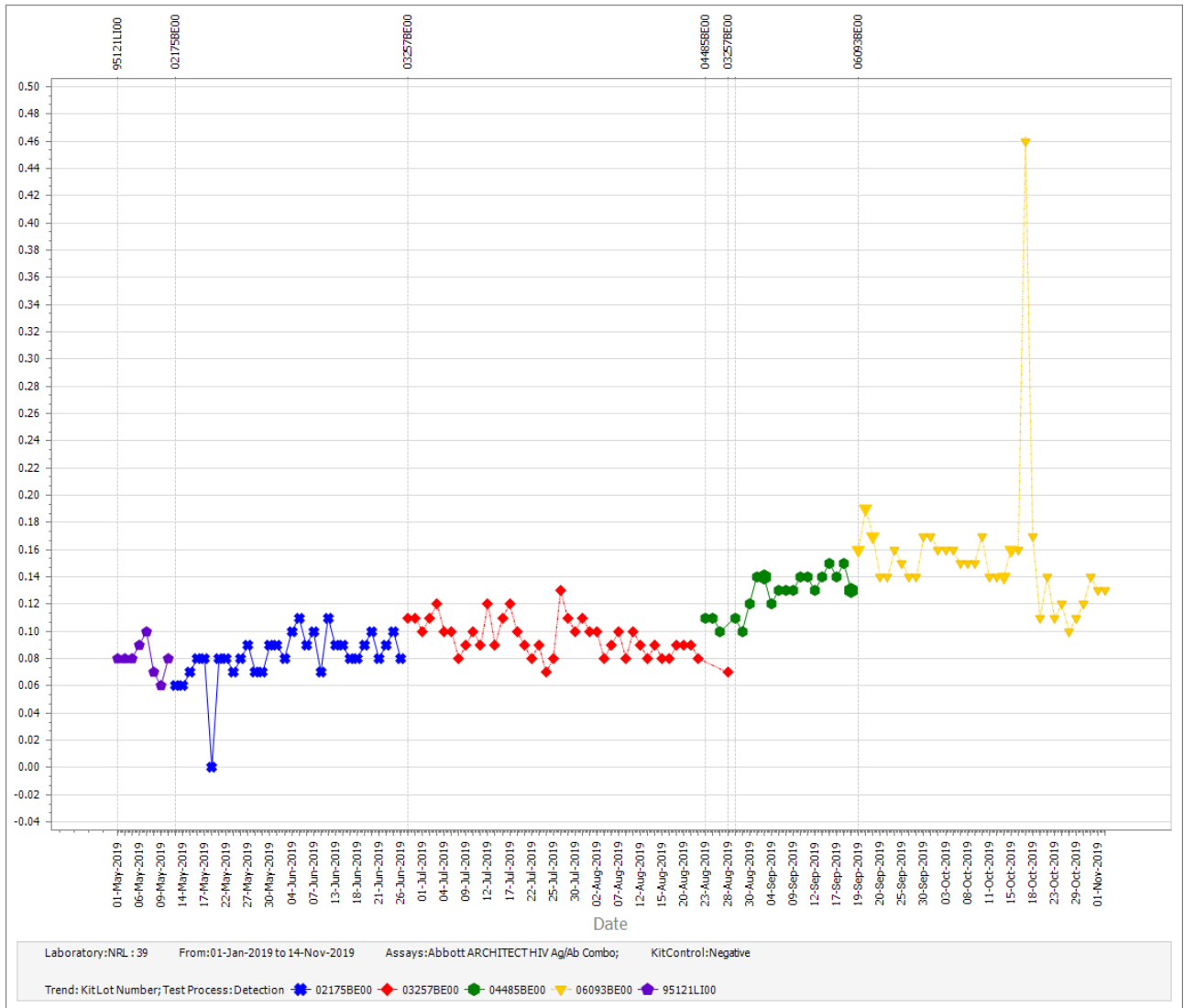


Figure 5: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Negative Kit Control.

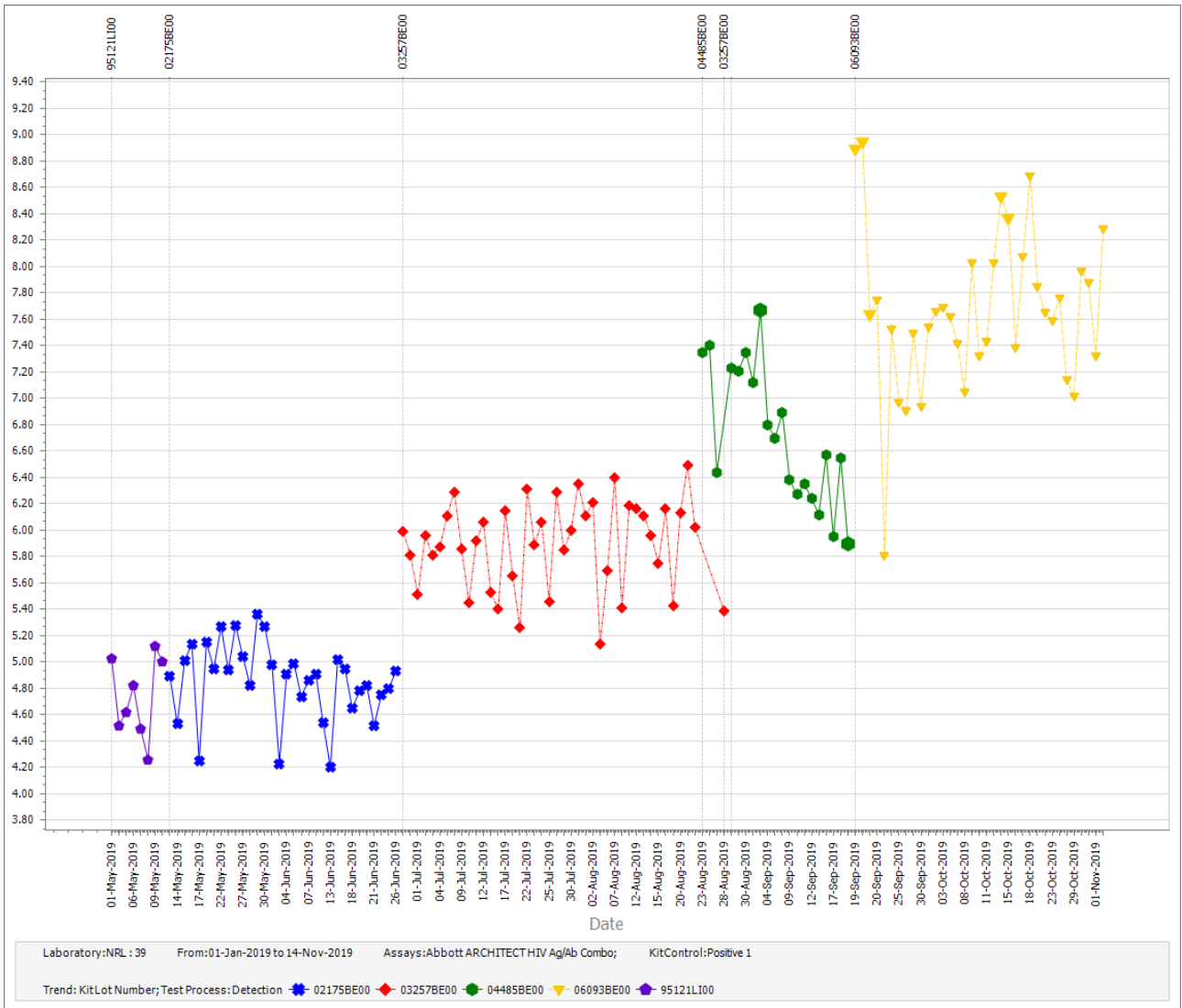


Figure 6: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 1 Kit Control.

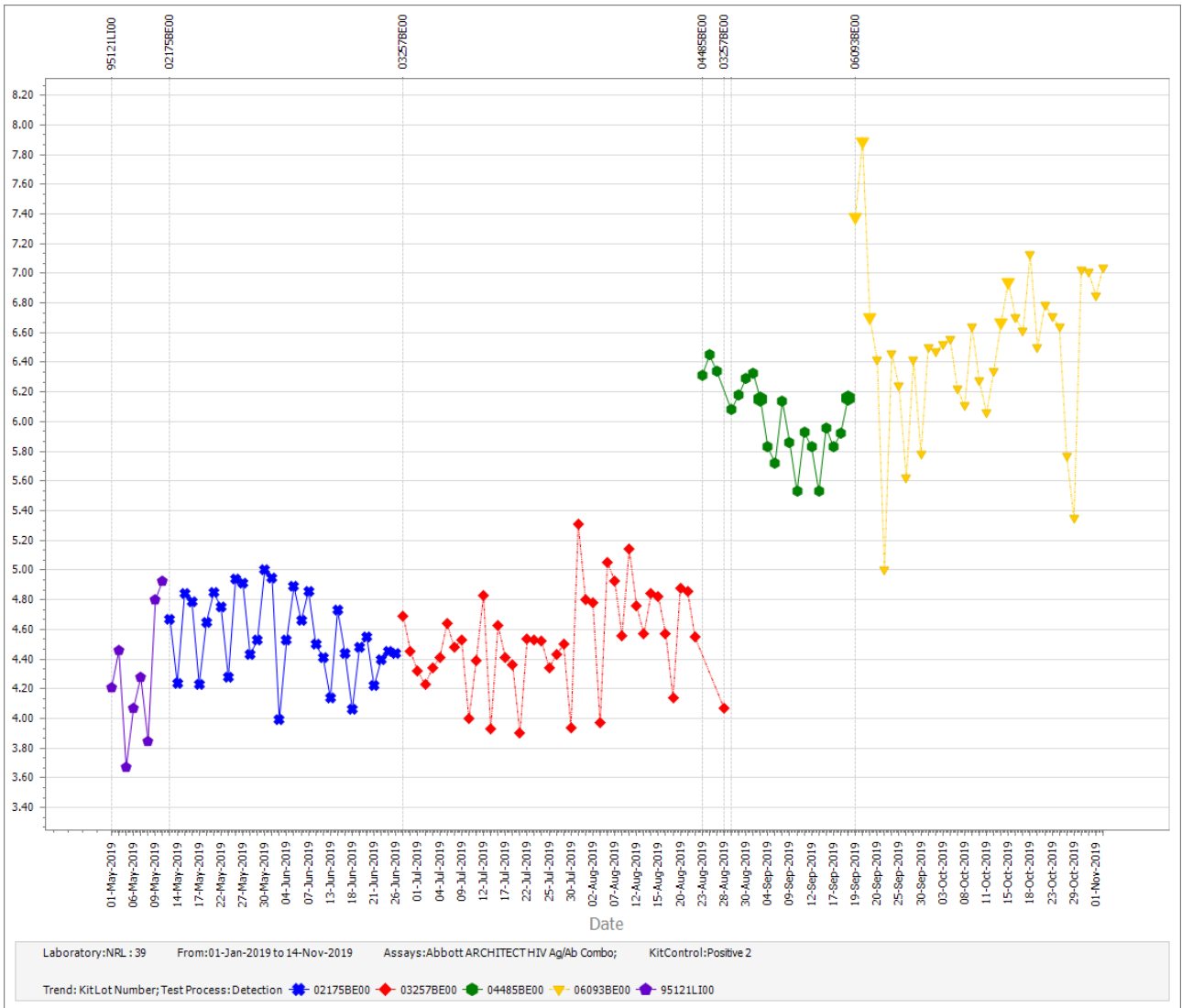


Figure 7: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 2 Kit Control.

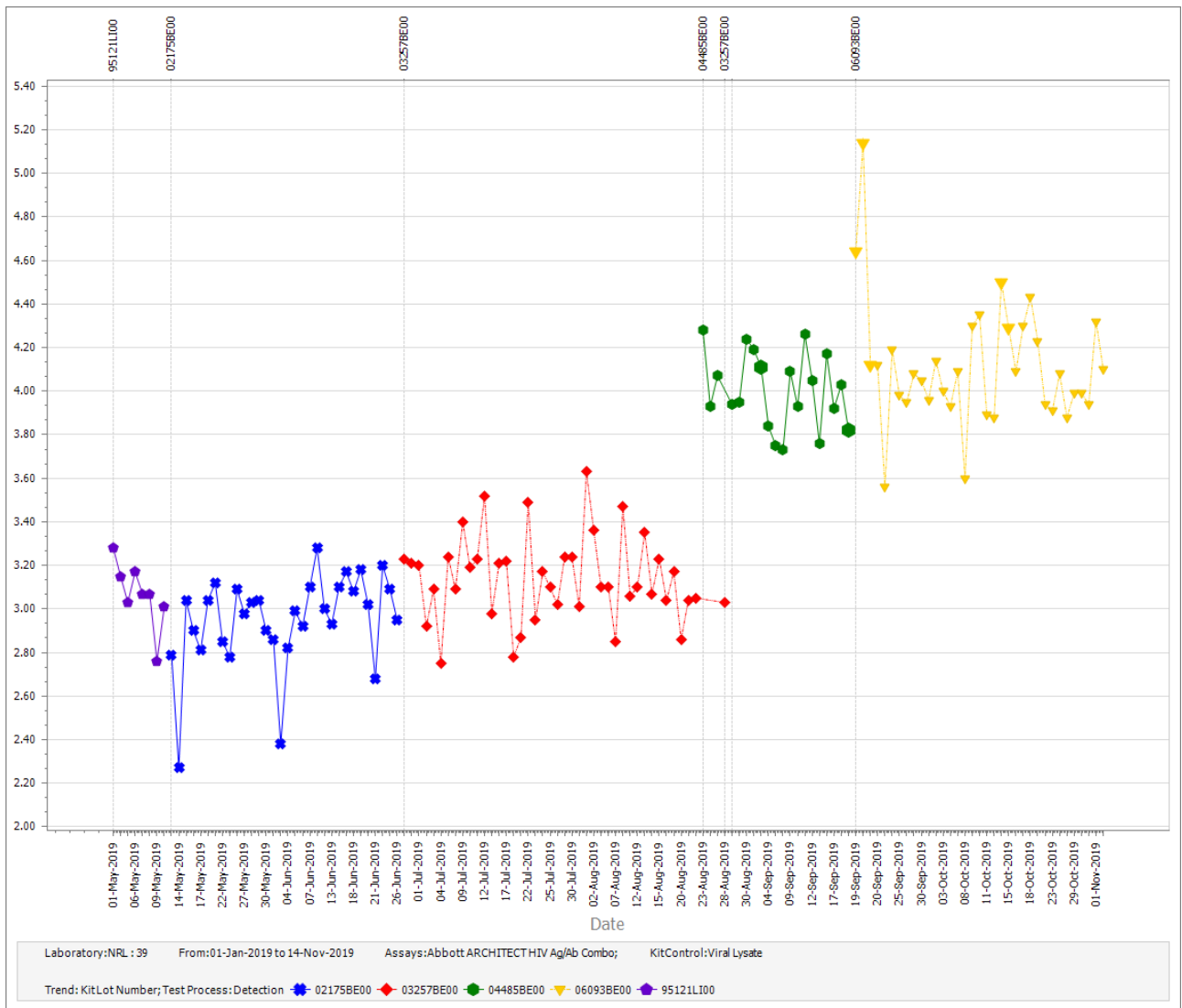


Figure 8: Participant 39 data for Abbott ARCHITECT HIV Ag/Ab Combo, Positive 3 (Viral Lysate) Kit Control.

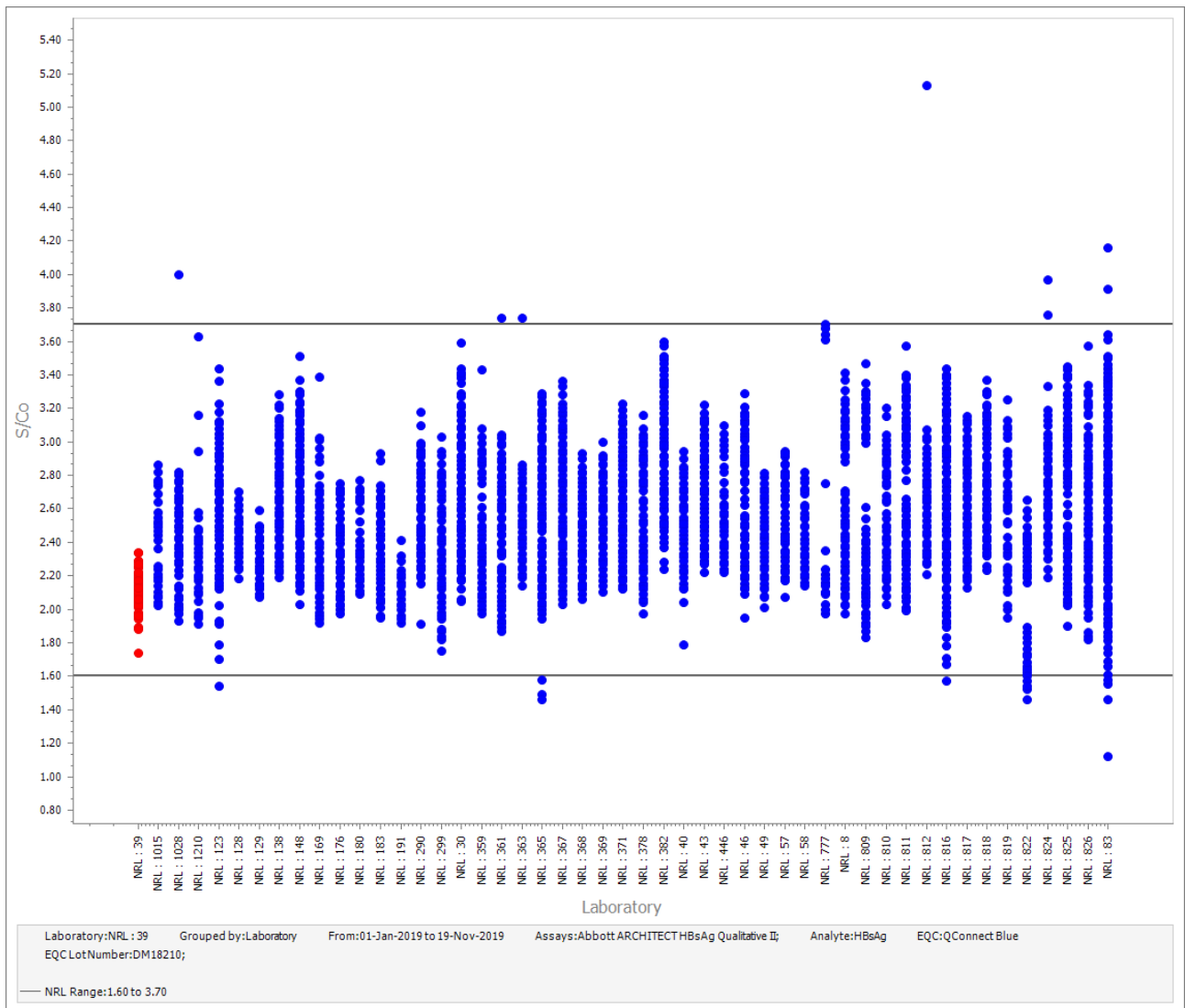


Figure 9: Participant 39 data for Abbott ARCHITECT HBsAg Qualitative II, QConnect Blue:DM18210 by participant.

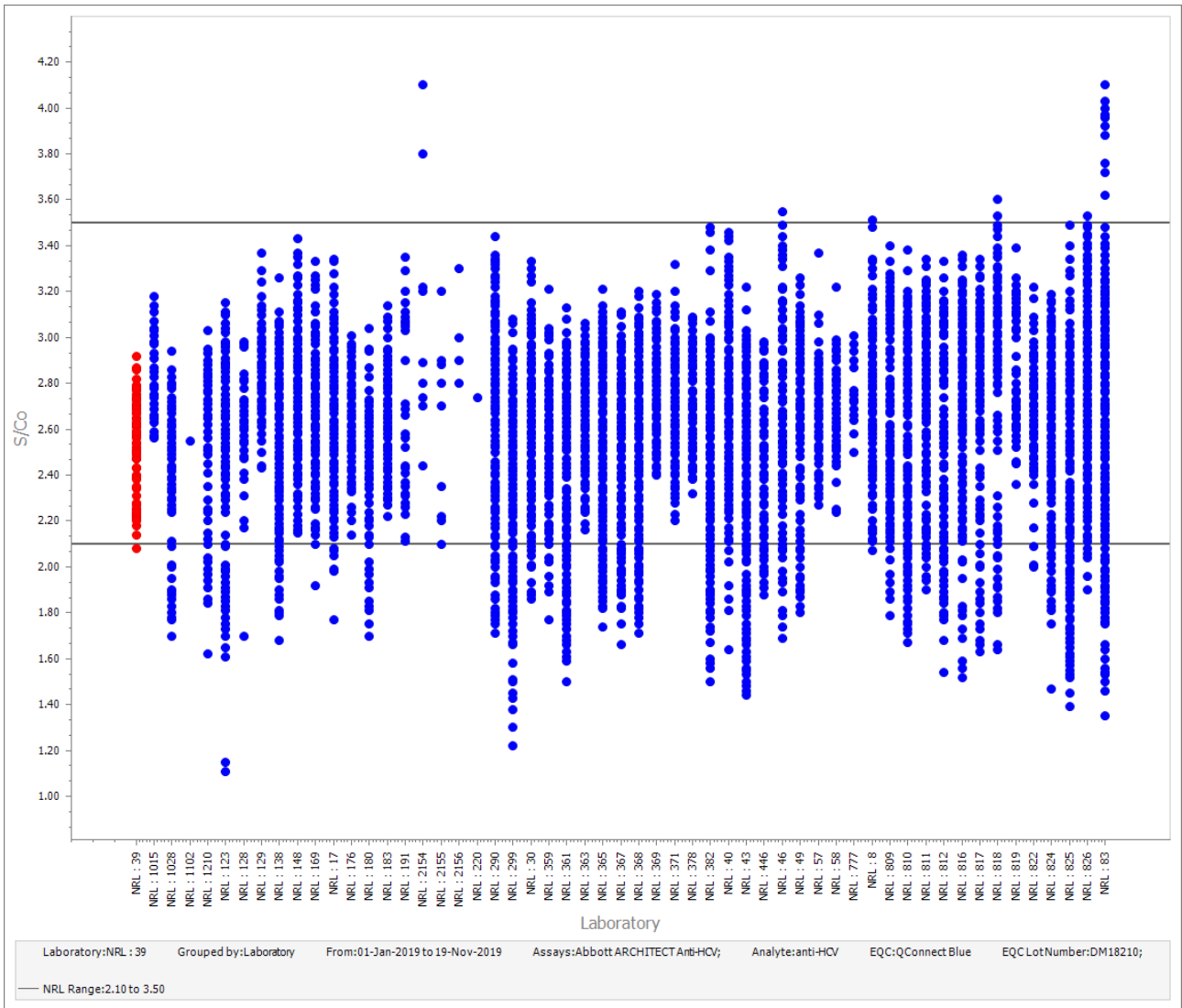


Figure 10: Participant 39 data for Abbott ARHCITECT Anti-HCV, QConnect Blue:DM18210 by participant.

Laboratory	Date	Operator	Instrument Type	Reagent Lot Number	Result
NRL : 39	8/21/2019	AJ	ARCHITECT	03257BE00	5.43
NRL : 39	8/22/2019	AP	ARCHITECT	03257BE00	5.10
NRL : 39	8/23/2019	EMF	ARCHITECT	04485BE00	6.10
NRL : 39	8/26/2019	AP	ARCHITECT	04485BE00	6.28
NRL : 39	8/27/2019	EMF	ARCHITECT	04485BE00	6.12
NRL : 39	8/28/2019	AJ	ARCHITECT	04485BE00	6.44
NRL : 39	8/29/2019	EMF	ARCHITECT	04485BE00	6.04
NRL : 39	8/30/2019	AJ	ARCHITECT	04485BE00	6.38
NRL : 39	9/2/2019	EMF	ARCHITECT	04485BE00	6.34
NRL : 39	9/3/2019	EMF	ARCHITECT	04485BE00	6.55
NRL : 39	9/4/2019	AJ	ARCHITECT	04485BE00	5.80
NRL : 39	9/5/2019	EMF	ARCHITECT	04485BE00	5.76
NRL : 39	9/6/2019	AP	ARCHITECT	04485BE00	6.21
NRL : 39	9/9/2019	EMF	ARCHITECT	04485BE00	6.35
NRL : 39	9/10/2019	EMF	ARCHITECT	04485BE00	6.23
NRL : 39	9/11/2019	AP	ARCHITECT	04485BE00	6.48
NRL : 39	9/12/2019	AJ	ARCHITECT	04485BE00	5.97
NRL : 39	9/13/2019	AJ	ARCHITECT	04485BE00	5.68
NRL : 39	9/16/2019	AP	ARCHITECT	04485BE00	6.64
NRL : 39	9/17/2019	AJ	ARCHITECT	04485BE00	6.08
NRL : 39	9/18/2019	AJ	ARCHITECT	04485BE00	5.89
NRL : 39	9/19/2019	EMF	ARCHITECT	06093BE00	6.90
NRL : 39	9/23/2019	AJ	ARCHITECT	06093BE00	5.60
NRL : 39	9/24/2019	AJ	ARCHITECT	06093BE00	6.78
NRL : 39	9/25/2019	AP	ARCHITECT	06093BE00	6.83
NRL : 39	9/26/2019	EMF	ARCHITECT	06093BE00	6.78
NRL : 39	9/27/2019	EMF	ARCHITECT	06093BE00	6.68
NRL : 39	9/30/2019	AJ	ARCHITECT	06093BE00	6.45
NRL : 39	10/1/2019	AJ	ARCHITECT	06093BE00	6.84
NRL : 39	10/2/2019	AJ	ARCHITECT	06093BE00	6.78
NRL : 39	10/3/2019	EMF	ARCHITECT	06093BE00	6.81
NRL : 39	10/4/2019	EMF	ARCHITECT	06093BE00	7.07
NRL : 39	10/7/2019	EMF	ARCHITECT	06093BE00	6.41
NRL : 39	10/8/2019	AJ	ARCHITECT	06093BE00	6.35
NRL : 39	10/9/2019	AJ	ARCHITECT	06093BE00	7.65
NRL : 39	10/10/2019	AP	ARCHITECT	06093BE00	6.97
NRL : 39	10/11/2019	EMF	ARCHITECT	06093BE00	6.89
NRL : 39	10/14/2019	EMF	ARCHITECT	06093BE00	6.71
NRL : 39	10/15/2019	EMF	ARCHITECT	06093BE00	7.22
NRL : 39	10/16/2019	AP	ARCHITECT	06093BE00	7.05
NRL : 39	10/17/2019	AJ	ARCHITECT	06093BE00	7.70
NRL : 39	10/18/2019	AJ	ARCHITECT	06093BE00	7.52
NRL : 39	10/21/2019	EMF	ARCHITECT	06093BE00	7.42
NRL : 39	10/22/2019	AP	ARCHITECT	06093BE00	7.31
NRL : 39	10/23/2019	AJ	ARCHITECT	06093BE00	7.30
NRL : 39	10/28/2019	AP	ARCHITECT	06093BE00	4.31
NRL : 39	10/28/2019	AP	ARCHITECT	06093BE00	6.69
NRL : 39	10/29/2019	EMF	ARCHITECT	06093BE00	6.68
NRL : 39	10/30/2019	AJ	ARCHITECT	06093BE00	7.32
NRL : 39	10/31/2019	AJ	ARCHITECT	06093BE00	7.58
NRL : 39	11/1/2019	EMF	ARCHITECT	06093BE00	6.96
NRL : 39	11/4/2019	EMF	ARCHITECT	06093BE00	7.17
NRL : 39	11/5/2019	AJ	ARCHITECT	06093BE00	7.48
NRL : 39	11/6/2019	AP	ARCHITECT	06093BE00	5.54
NRL : 39	11/7/2019	EMF	ARCHITECT	06093BE00	7.12
NRL : 39	11/8/2019	AJ	ARCHITECT	06093BE00	7.31
NRL : 39	11/11/2019	AJ	ARCHITECT	06093BE00	6.80
NRL : 39	11/12/2019	AJ	ARCHITECT	06093BE00	5.91
NRL : 39	11/14/2019	BJB	ARCHITECT	06093BE00	5.04

**Table 1:**

Laboratory: NRL : 39  
From: 01-Jan-2019 to 14-Nov-2019  
Assays: Abbott ARCHITECT HIV Ag/Ab Combo;  
Analyte: HIV p24 Ag/Anti-HIV  
EQC: QConnect Blue  
EQC Lot Number: DM18210;



Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
<b>NRL : 39</b>	<b>59</b>	<b>6.54</b>	<b>0.70</b>	<b>5.14</b>	<b>7.94</b>	<b>4.31</b>	<b>7.70</b>	<b>10.69</b>
NRL : 1015	71	4.22	0.20	3.82	4.62	3.72	4.58	4.77
NRL : 1028	157	5.20	0.63	3.95	6.46	4.00	6.52	12.05
NRL : 12	1	2.66	NA	NA	NA	2.66	2.66	NA
NRL : 1210	71	4.69	0.59	3.51	5.87	3.45	5.99	12.60
NRL : 123	144	4.32	0.74	2.85	5.80	1.80	5.65	17.03
NRL : 128	61	4.21	0.24	3.73	4.68	3.59	4.70	5.66
NRL : 129	117	4.62	0.38	3.87	5.38	3.60	5.43	8.20
NRL : 138	369	4.48	0.36	3.76	5.21	2.89	5.38	8.07
NRL : 148	197	4.74	0.62	3.49	5.98	2.61	6.36	13.15
NRL : 169	208	4.90	0.55	3.80	6.00	3.07	6.21	11.21
NRL : 17	190	4.62	0.47	3.68	5.57	3.36	5.89	10.21
NRL : 176	128	4.80	0.59	3.62	5.98	3.54	6.18	12.32
NRL : 180	107	5.21	0.52	4.16	6.26	3.72	5.93	10.06
NRL : 183	212	4.83	0.54	3.75	5.92	3.87	6.04	11.24
NRL : 191	43	5.31	0.56	4.19	6.44	4.14	6.31	10.58
NRL : 2155	10	2.96	0.50	1.97	3.96	2.40	3.80	16.73
NRL : 2156	10	3.28	0.63	2.02	4.54	2.10	4.10	19.18
NRL : 290	247	4.45	0.43	3.60	5.30	3.54	5.55	9.57
NRL : 299	231	4.38	0.79	2.81	5.96	2.84	5.96	17.97
NRL : 30	303	4.83	0.76	3.32	6.34	1.97	6.88	15.62
NRL : 359	225	4.44	0.45	3.53	5.34	3.18	5.45	10.17
NRL : 36	163	4.46	0.68	3.09	5.83	3.44	5.74	15.32
NRL : 361	346	4.51	0.50	3.50	5.52	3.59	5.72	11.18
NRL : 363	330	4.58	0.37	3.84	5.31	3.71	5.41	8.02
NRL : 365	659	4.49	0.52	3.46	5.52	2.94	5.62	11.47
NRL : 367	328	4.47	0.47	3.53	5.41	3.38	5.95	10.52
NRL : 368	323	4.75	0.46	3.83	5.67	3.86	5.93	9.67
NRL : 369	192	4.81	0.29	4.23	5.39	4.05	5.36	6.03
NRL : 371	426	4.36	0.49	3.39	5.34	3.21	5.48	11.19
NRL : 378	134	4.67	0.39	3.90	5.44	3.07	5.30	8.24
NRL : 382	292	4.00	0.49	3.02	4.98	3.16	5.18	12.22
NRL : 40	220	4.91	0.71	3.49	6.32	2.62	6.35	14.43
NRL : 43	325	4.12	0.34	3.44	4.80	2.45	5.00	8.23
NRL : 446	105	4.24	0.23	3.78	4.69	3.71	4.84	5.36
NRL : 46	175	4.74	0.60	3.55	5.93	3.30	5.96	12.58
NRL : 49	163	5.19	0.67	3.85	6.53	3.17	6.01	12.90
NRL : 57	118	4.69	0.54	3.60	5.78	3.87	5.91	11.59
NRL : 58	107	4.87	0.49	3.90	5.85	3.92	5.83	9.99
NRL : 777	23	5.19	0.58	4.04	6.34	3.30	5.74	11.10
NRL : 8	169	4.28	0.25	3.78	4.79	3.73	5.07	5.89
NRL : 809	246	4.28	0.51	3.25	5.31	2.92	5.55	11.99
NRL : 810	230	4.26	0.45	3.37	5.15	3.39	5.42	10.47
NRL : 811	282	4.11	0.44	3.24	4.98	2.89	5.40	10.61
NRL : 812	138	4.93	0.47	3.99	5.87	3.88	5.83	9.53
NRL : 816	382	4.13	0.48	3.18	5.09	3.28	5.17	11.55
NRL : 817	227	4.30	0.28	3.75	4.85	3.73	5.18	6.40
NRL : 818	156	4.57	0.48	3.62	5.52	3.61	5.64	10.41
NRL : 819	60	5.44	0.53	4.37	6.50	4.49	6.45	9.80
NRL : 822	127	3.99	0.70	2.60	5.39	2.19	5.23	17.50
NRL : 824	176	4.27	0.53	3.21	5.34	3.43	5.43	12.45
NRL : 825	287	3.95	0.54	2.88	5.03	2.64	5.01	13.63
NRL : 826	292	4.30	0.45	3.40	5.20	3.29	5.40	10.42
NRL : 83	1113	4.32	0.52	3.28	5.36	2.01	5.94	12.03
Totals	11475	4.49	0.61	3.26	5.72	1.80	7.70	13.66

**Table 2:**

Laboratory: NRL : 39  
 Grouped by: Laboratory  
 From: 01-Jan-2019 to 14-Nov-2019  
 Assays: Abbott ARCHITECT HIV Ag/Ab Combo;  
 Analyte: HIV p24 Ag/Anti-HIV  
 EQC: QConnect Blue  
 EQC Lot Number: DM18210;

<b>Date</b>	<b>Reagent Lot</b>	<b>Calibrator Lot</b>
23/08/2019	04485BE00	02130BE00
3/09/2019	04485BE00	02130BE00
19/09/2019	06093BE00	02130BE00
15/10/2019	06093BE00	02130BE00
14/11/2019	06093BE00	14123BE00

Table 3: Participant 39 Calibration data for Abbott ARCHITECT HIV Ag/Ab Combo; QConnect Blue:DM18210.