



QC SEROLOGY INVESTIGATION PMM-QC-713

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- 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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1 Introduction

Participant 57 completed an evaluation of QConnect QC products and EDCNet. This report is a summary of the testing data submitted into EDCNet from 01 January to 30 September 2019. The Laboratory noted two assays, DiaSorin LIAISON Measles IgG and DiaSorin LIAISON VZV IgM, that they requested required further investigation regarding their results and how they compare to peer group data.

2 Findings

- **Figure 1:** Participant 57 data for DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131.
- **Figure 2:** Participant 57 data for DiaSorin LIAISON VZV IgG, QConnect Pediatric G DM18131.
- **Figure 3:** Participant 57 data for Roche Elecsys Anti-HBe, QConnect HEPR DM17216.
- **Figure 4:** Participant 57 data for Roche Elecsys HIV Duo, QConnect RED DM18129.
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- **Figure 6:** Participant 57 data Roche Elecsys HIV combi PT, QConnect RED DM18129.
- **Figure 7:** Participant 57 data Roche Elecsys HIV combi PT, QConnect RED DM18129 in comparison with peer group by reagent lot.
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- **Figure 13:** Participant 57 data (red) for Roche Elecsys Anti-HBe, QConnect HEP R DM17216 in comparison with peer group data by participant.
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- **Figure 18:** Participant 57 data (red) Roche Elecsys HBeAg, QConnect HEPA2 DM18229 in comparison with peer group data by participant.

- **Table 1:** Summary data of %CV for assays and QConnect controls tested by Participant 57 in comparison with peer group data.
- **Table 2:** Participant 57 data DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131 by instrument.
- **Table 3:** Participant 57 data (red) for Roche Elecsys Anti-HAV, QConnect HEP R DM17216 in comparison with peer group data by participant.
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- **Table 5:** Participant 57 data (red) for Roche Elecsys Anti-HBs II, QConnect HEP R DM17216 in comparison with peer group data by participant.
- **Table 6:** Participant 57 data (red) for Roche Elecsys Anti-HAV IgM, QConnect HEPA2 DM18229 in comparison with peer group data by participant.
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- **Table 8:** Participant 57 data (red) Roche Elecsys HBeAg, QConnect HEPA2 DM18229 in comparison with peer group data by participant.

3 Discussion

Data entered into EDCNet by Participant 57 between 01 January until 30 September 2019 were investigated to provide an overall summary of QC samples and EDCNet performance.

Out of 43 Assay/QC combinations tested and reviewed for Participant 57, nine had insufficient data to calculate %CV, the remaining 34 all had a %CV of <20%. Of the 34 combinations, 25 (73.5%) had a %CV of <10 and nine (26.5%) had a %CV of <20%. No Assay/EQC combination had a %CV >20%. (Table 1).

Six Assays showed a total of nine (9) data points falling outside limits. Four assays, DiaSorin LIAISON Measles IgG (Figure 1) DiaSorin LIAISON VZV IgG (Figure 2) Roche Elecsys Anti-HBe (Figure 3) and Roche Elecsys HIV Duo (Figure 4) had $\pm 3SD$ limits calculated and were subject to more frequent changes as more data were entered into EDCNet. On investigation into these data, it was concluded that for each assay the data represent random error and were not representative of a current or an ongoing issue. The two remaining assays, DiaSorin LIAISON XL MUREX HCV Ab (Figure 5) and Roche Elecsys HIV combi PT (Figure 6) had QConnect Limits calculated, which include historical data and therefore provide more appropriate and reliable ranges. For the DiaSorin LIAISON XL MUREX HCV Ab assay one data point fell below QConnect Limits, the laboratory reported in EDCNet that their kit controls were within range on the day of testing. Subsequent QConnect data were all in range (Figure 5) and thus the single out of range data point was attributed to random error. The Roche Elecsys HIV combi PT assay showed two data points below QConnect limits. The two data

points were isolated to one reagent lot, number 330703500. No other participant in the peer group had tested using this reagent lot and reagent lot variation was most likely the cause for these data falling outside QConnect Limits (Figure 7).

Regarding the two assays Participant 57 requested for closer investigation. For the DiaSorin LIAISON Measles IgG assay, Participant 57 highlighted the low spikes falling outside of the limits (Figure 8) and asked whether peer group data showed similar patterns. Participant 57 were testing on two LIAISON XL instruments and a total of three data points fell below the limits across both instruments. As illustrated in (Figure 9) the two instruments were performing differently when compared to each other with LIAISON XL 4 showing more variation than LIAISON XL 5. Participant 57 commented (anecdotally) that their kit control data did occasionally show similar low spikes, however still remained within limits. No kit control data were supplied in EDCNet so no comparison could be made. Table 2 illustrates that Participant 57 had a higher SD and %CV than that of the peer group, confirming the higher variation seen in Figure 10. Participant 57 had submitted 29 data points only for this assay and this, in addition to the instrument variation, was the likely the reason for the higher %CV. Participants within the peer group did not show similar low spikes or variation in data, which indicates a laboratory specific issue as the cause of variation.

For the second assay, DiaSorin LIAISON VZV IgM, Participant 57 queried their results of >2.30 IV (Figure 11). The QConnect sample used on this assay was QConnect VZV M. All QConnect samples must be handled as per the assay IFU when storing, preparing and testing. From the data submitted by Participant 57 it was highly likely that the QConnect sample has not been tested as per the IFU and the QC sample was loaded and tested as a DiaSorin LIAISON kit control sample. DiaSorin LIAISON kit controls do not undergo the same testing procedure as a patient sample on the DiaSorin LIAISON VZV IgM assay. Patient samples are diluted while the kit controls are not. The results of >2.30 seen for Participant 57 were due to the QConnect sample having not been diluted.

There were limited data entered for assays testing with QConnect HEPR and HEPA2. It was reported (anecdotally) by the participant that this was possibly due to operator error in pipetting too much volume into the sample cup for testing leading to them running out of the sample. HEPR DM17216 was tested on three assays, Roche Elecsys Anti-HAV (Figure 12 & Table 3), Roche Elecsys Anti-HBe (Figure 13 & Table 4), and Roche Elecsys Anti-HBs II (Figure 15 & Table 5). HEPA2 DM18229 was also tested on three assays, Roche Elecsys Anti-HAV IgM (Figure 16 & Table 6), Roche Elecsys Anti-HBc IgM (Figure 17 & Table 7), and Roche Elecsys HBeAg (Figure 8 & Table 8). All assays showed similar mean values to that of other participants and total peer group data. The only notable difference in data from

Participant 57 and peer group data was seen on the Roche Elecsys Anti-HBe assay, this was identified to be due to reagent lot variation (Figure 14).

4 Recommendations

NRL recommends Participant 57 continue the use of QConnect products and EDCNet services to evaluate and monitor variation in their laboratory testing systems.

NRL recommends Participant 57 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 Participant 57 submit kit controls into EDCNet, allowing for more complete reviewing and investigations.

NRL recommends Participant 57 investigate whether the product IFU and correct laboratory procedures are being followed by all operators, specifically in relation to the use of QConnect VZV M.

NRL recommends participants experiencing aberrant QC results or who have any queries about QConnect contact the NRL for detailed investigations by contacting gconnect@nrlquality.org.au.

SYSTEM	ASSAY	EQC	LOT	LAB %CV	Peer Grp %CV
Abbot ARCHITECT	Abbott ARCHITECT Anti-HBc II	BLUE	DM18210	N/A	6.84
			DM19001	2.88	4.59
	Abbott ARCHITECT Anti-HCV	BLUE	DM18021	5.42	13.4
			DM18210	6.72	13.72
			DM19001	5.97	9.97
	Abbott ARCHITECT HBsAg Qualitative II	BLUE	DM17155	N/A	9.04
			DM18021	3.64	10.56
			DM18210	8.94	13.21
			DM19001	3.28	5.44
	Abbott ARCHITECT HIV Ag/Ab Combo	BLUE	DM18021	9.27	13.14
		DM18210	11.6	13.32	
		DM19001	4.49	10.03	
DiaSorin LIAISON	DiaSorin LIAISON Biotrin Parvovirus B19 IgG	Pediatric G	DM18131	6.64	10.74
	DiaSorin LIAISON Biotrin Parvovirus B19 IgM	Parvo M	DM18028	10.2	18.16
	DiaSorin LIAISON CMV IgG II	ToRCHG	DM18102	12.7	12.85
	DiaSorin LIAISON CMV IgM II	ToRCHM	DM18132	6.65	8.11
	DiaSorin LIAISON EBNA IgG	ToRCHG	DM18102	4.03	10.4
	DiaSorin LIAISON EBV IgM	ToRCHM	DM18132	10.9	12.6
	DiaSorin LIAISON VCA IgG	ToRCHG	DM18102	10.6	10.32
	DiaSorin LIAISON HSV-1 Type Specific IgG	ToRCHG	DM18102	4.25	5.87
	DiaSorin LIAISON HSV-2 IgG	HSV2G	DM18002	4.53	11.7
	DiaSorin LIAISON Measles IgG	Pediatric G	DM18131	15.2	8.71
	DiaSorin LIAISON Measles IgM	Measles M	DM18030	5.16	19.56
	DiaSorin LIAISON Mumps IgG	Pediatric G	DM18131	3.39	9.98
	DiaSorin LIAISON Rubella IgG II	ToRCHG	DM18102	7.56	9.12
	DiaSorin LIAISON Rubella IgM	ToRCHM	DM18132	7.8	8.62
	DiaSorin LIAISON Toxo IgG II	ToRCHG	DM18102	6.76	10.13
	DiaSorin LIAISON Toxo IgM	ToRCHM	DM18132	3.74	13.62
	DiaSorin LIAISON Treponema Screen	BLUE	DM18210	3.25	3.83
	DiaSorin LIAISON VZV IgG	Pediatric G	DM18131	18.5	15.26
	DiaSorin LIAISON VZV IgM	VZV M	DM18029	10.6	18.94
	DiaSorin LIAISON XL MUREX HCV Ab	BLUE	DM18210	16.3	10.9
Roche ELECSYS	Roche Elecsys Anti-HAV	HEPR	DM17216	N/A	7.48
	Roche Elecsys Anti-HAV IgM	HEPA2	DM18229	N/A	9.7
	Roche Elecsys Anti-HBc IgM	HEPA2	DM18229	N/A	13.69
	Roche Elecsys Anti-HBc II	RED	DM18129	5.13	13.53
	Roche Elecsys Anti-HBe	HEPR	DM17216	N/A	6.18
	Roche Elecsys Anti-HBs II	HEPR	DM17216	N/A	9.99
	Roche Elecsys Anti-HCV II	RED	DM18129	7.09	5.53
	Roche Elecsys HBeAg	HEPA2	DM18229	N/A	10.01
	Roche Elecsys HBsAg II	RED	DM18129	6.49	11.82
	Roche Elecsys HIV combi PT	RED	DM18129	N/A	9.23
	Roche Elecsys HIV Duo	RED	DM18129	4.65	4.77

Table 1: Summary data of %CV for assays and QConnect controls tested by Participant 57 in comparison with peer group at time of generation of this report.

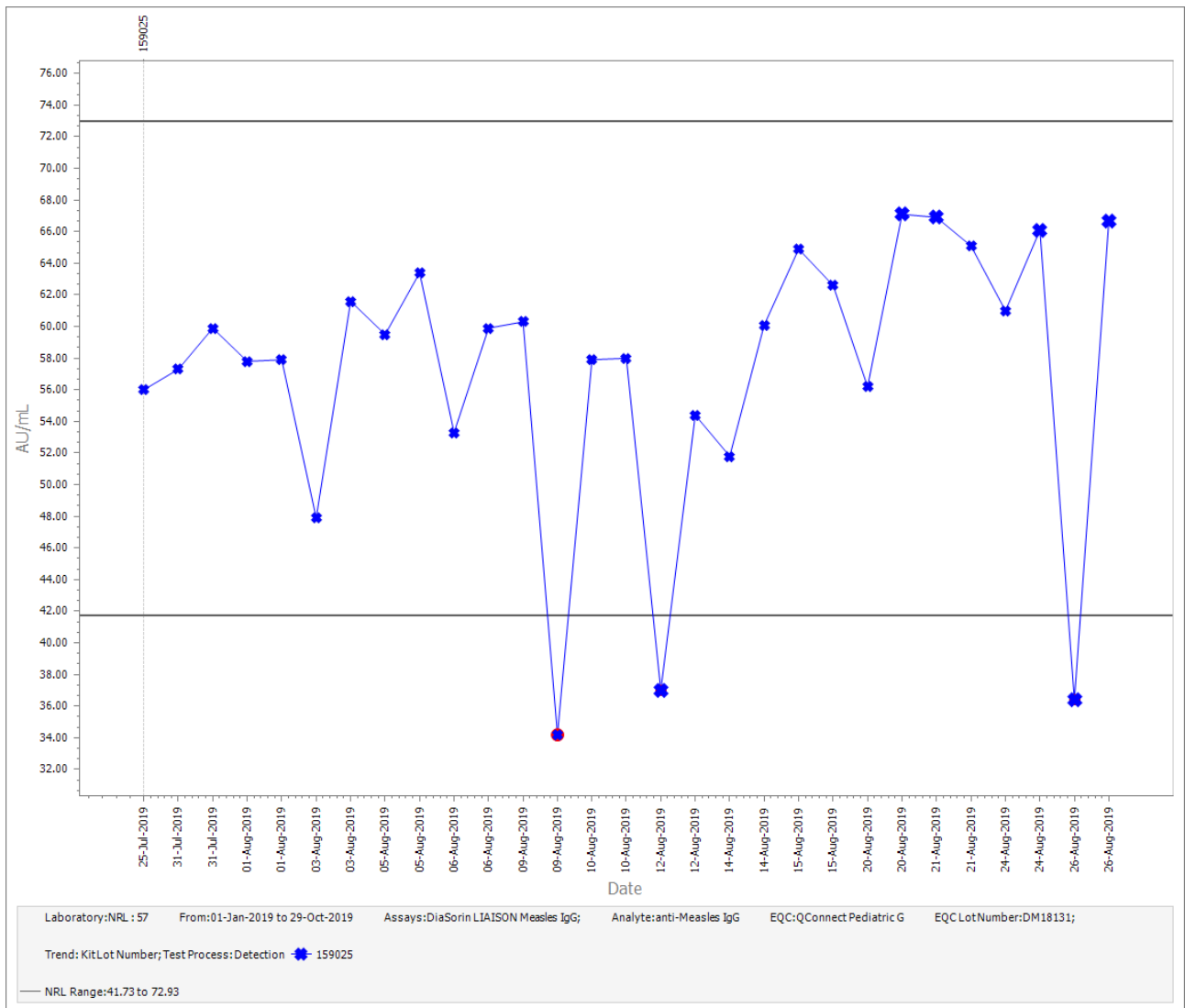


Figure 1: Participant 57 data for DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131.

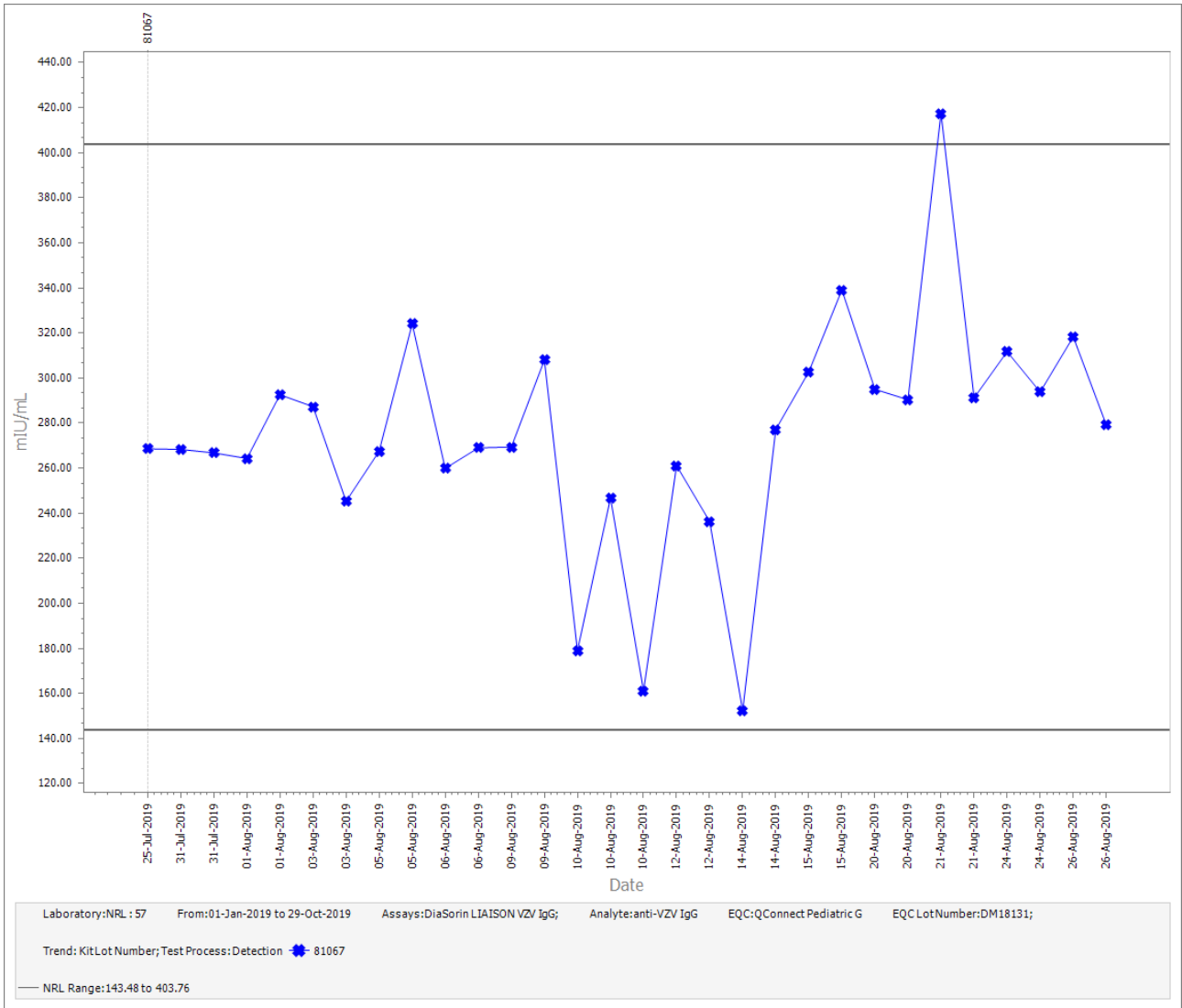


Figure 2: Participant 57 data for DiaSorin LIAISON VZV IgG, QConnect Pediatric G DM18131.

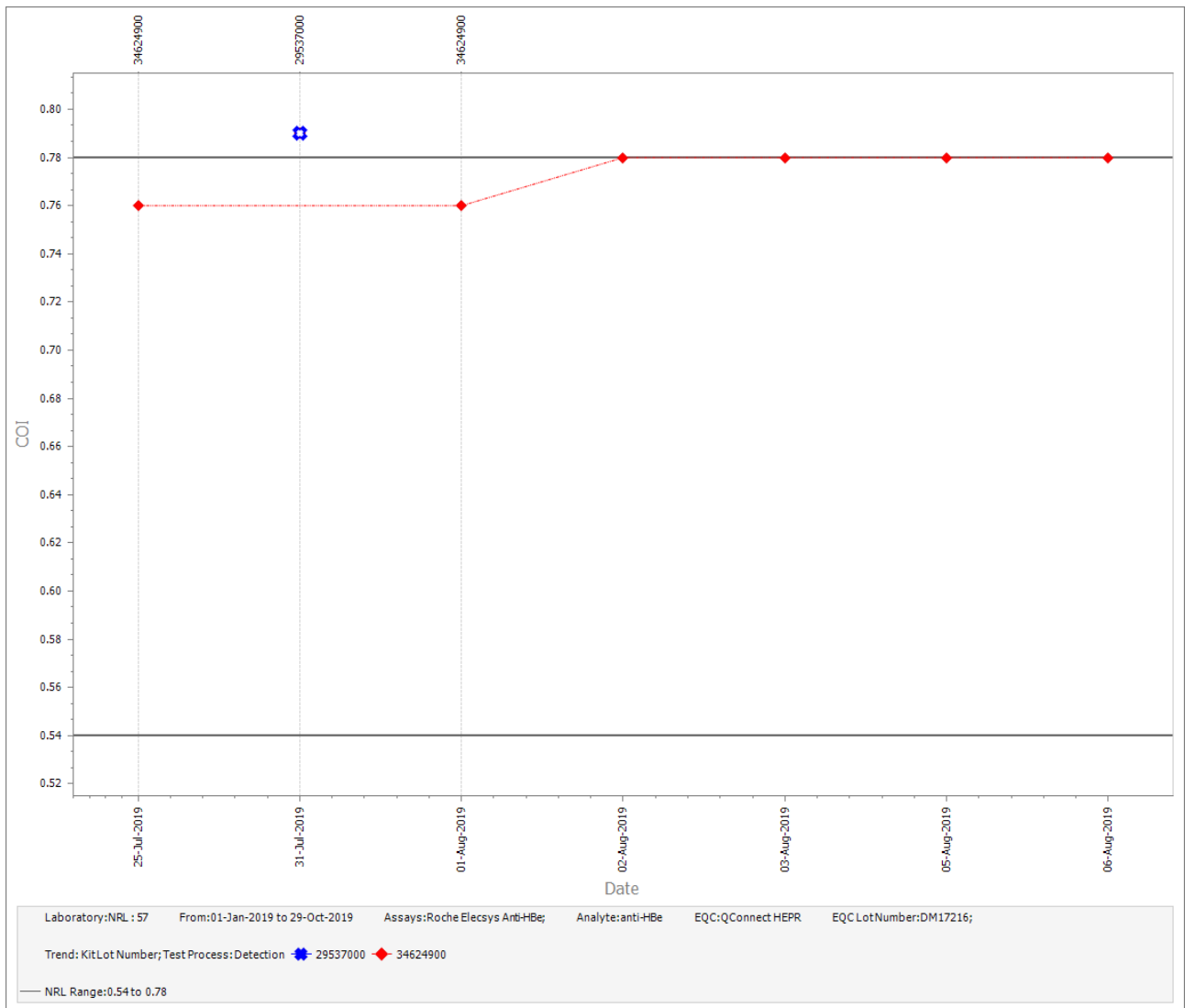


Figure 3: Participant 57 data for Roche Elecsys Anti-HBe, QConnect HEPR DM17216.

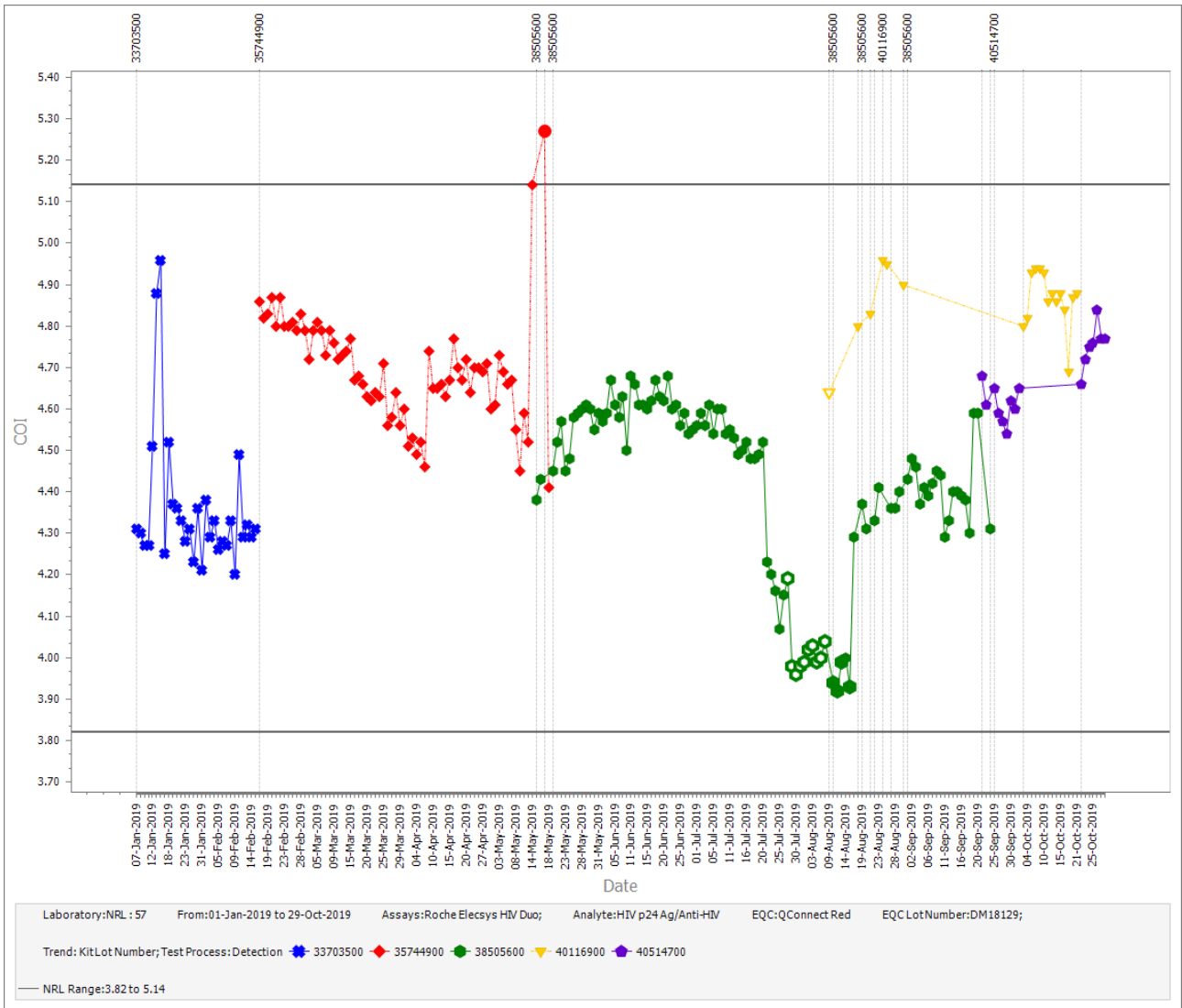


Figure 4: Participant 57 data for Roche Elecsys HIV Duo, QConnect RED DM18129.

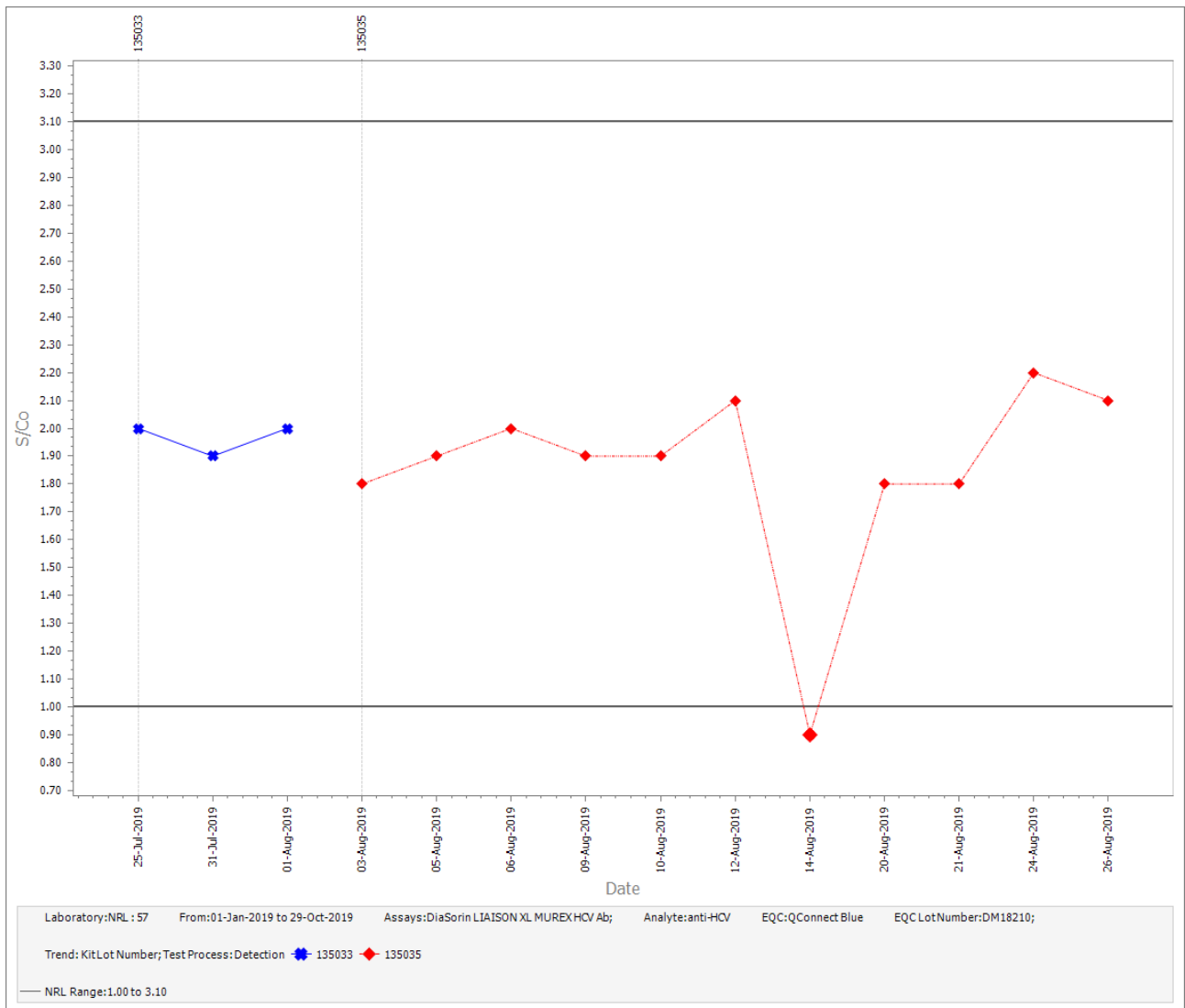


Figure 5: Participant 57 data DiaSorin LIAISON XL MUREX HCV Ab, QConnect BLUE DM18210.

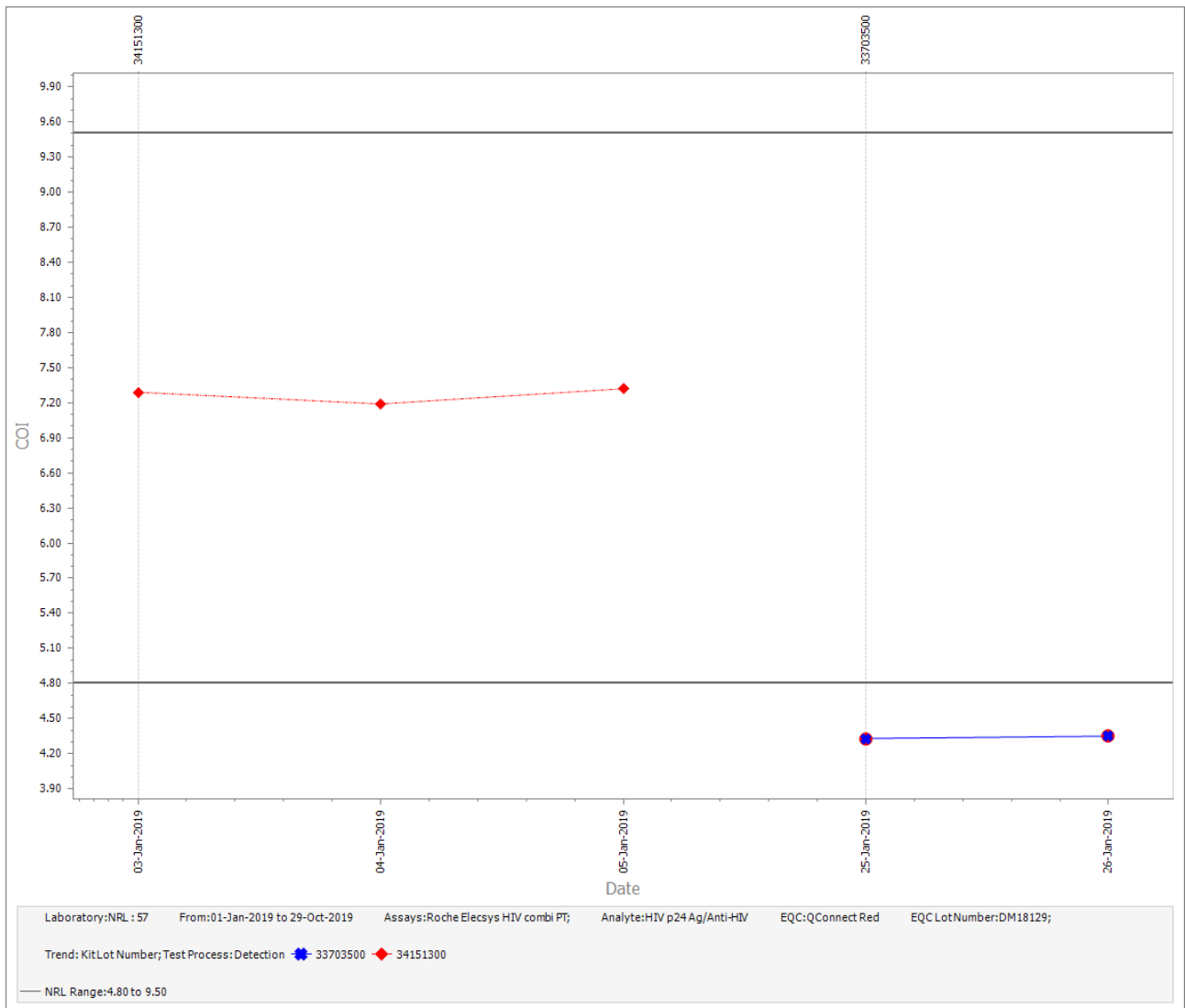


Figure 6: Participant 57 data Roche Elecsys HIV combi PT, QConnect RED DM18129.



Figure 7: Participant 57 data Roche Elecsys HIV combi PT, QConnect RED DM18129 in comparison with peer group by reagent lot.

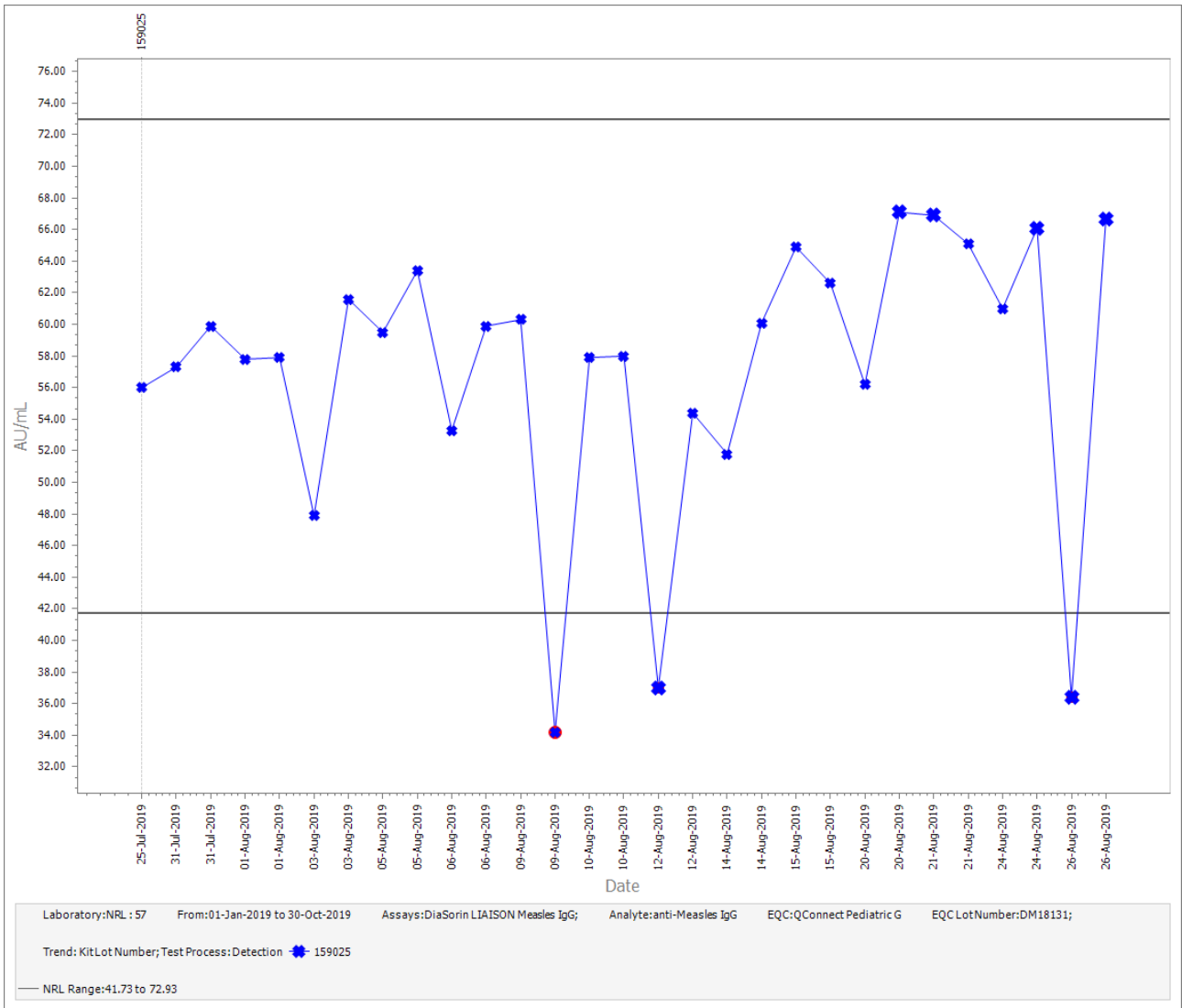


Figure 8: Participant 57 data DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131.

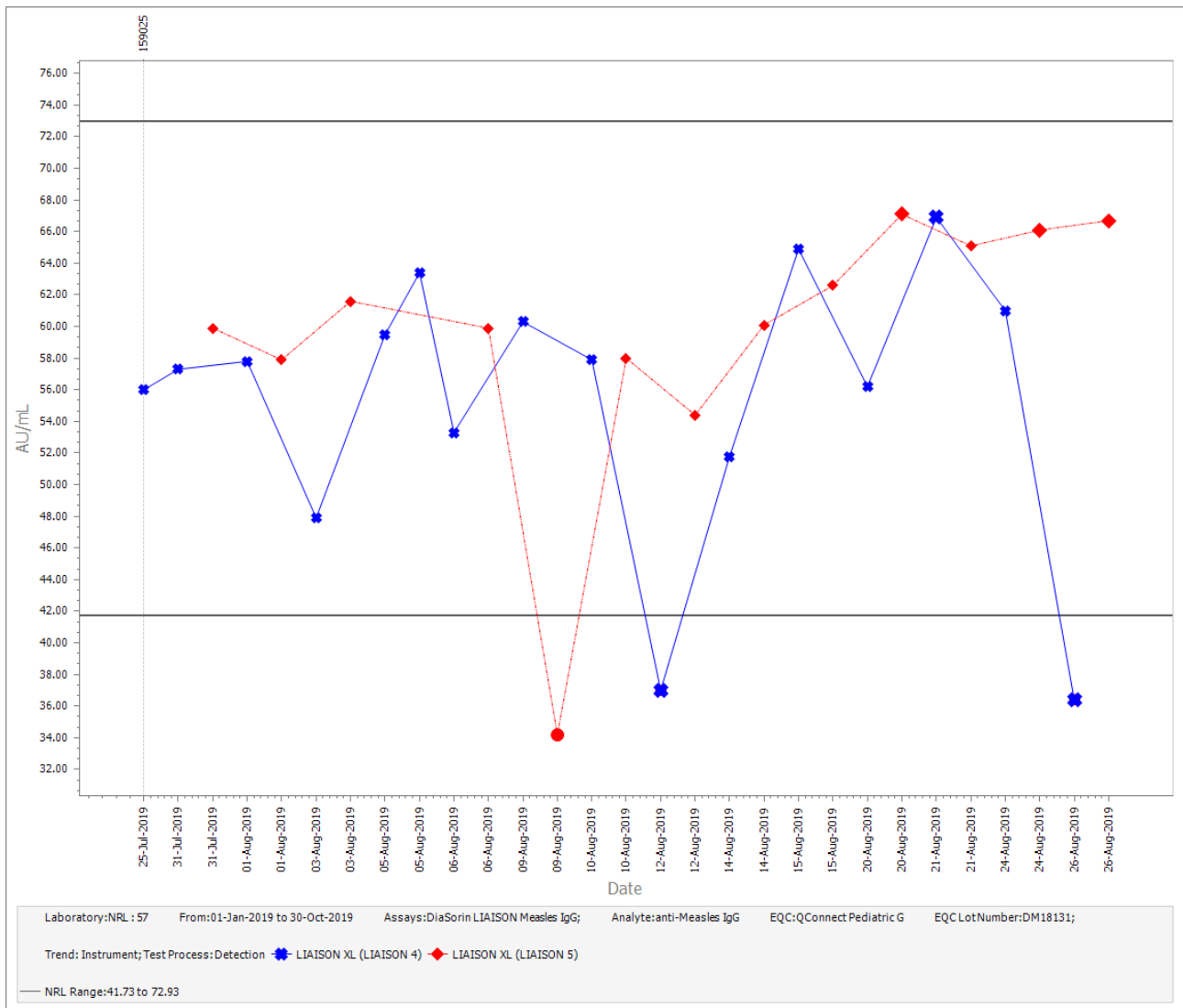


Figure 9: Participant 57 data DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131 by instrument.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 57	29	57.28	8.73	39.82	74.75	34.20	67.10	15.24
NRL : 1015	133	59.60	4.84	49.92	69.27	41.70	72.80	8.12
NRL : 129	166	56.68	4.44	47.81	65.55	46.90	69.40	7.82
NRL : 1300	3	55.73	NA	NA	NA	53.40	57.10	NA
NRL : 1307	2	36.25	NA	NA	NA	28.90	43.60	NA
NRL : 40	11	55.50	4.62	46.27	64.73	50.30	64.10	8.32
NRL : 66	87	55.46	3.83	47.81	63.11	42.60	63.80	6.90
Totals	431	57.25	5.29	46.66	67.83	28.90	72.80	9.25

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: DiaSorin LIAISON Measles IgG;
 Analyte: anti-Measles IgG
 EQC: QConnect Pediatric G
 EQC Lot Number: DM18131;

Table 2.

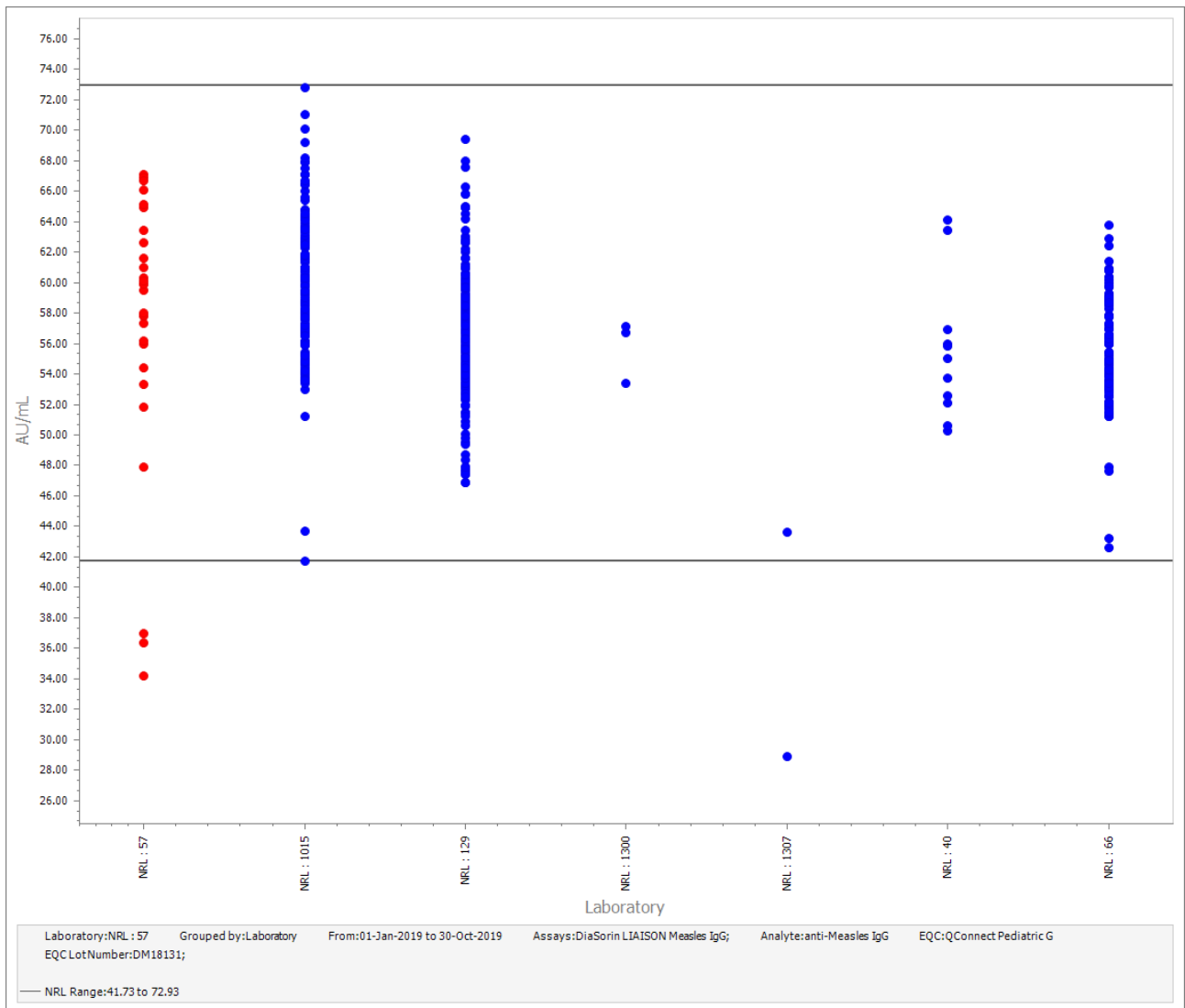


Figure 10: Participant 57 data DiaSorin LIAISON Measles IgG, QConnect Pediatric G DM18131 in comparison with peer group data by laboratory.

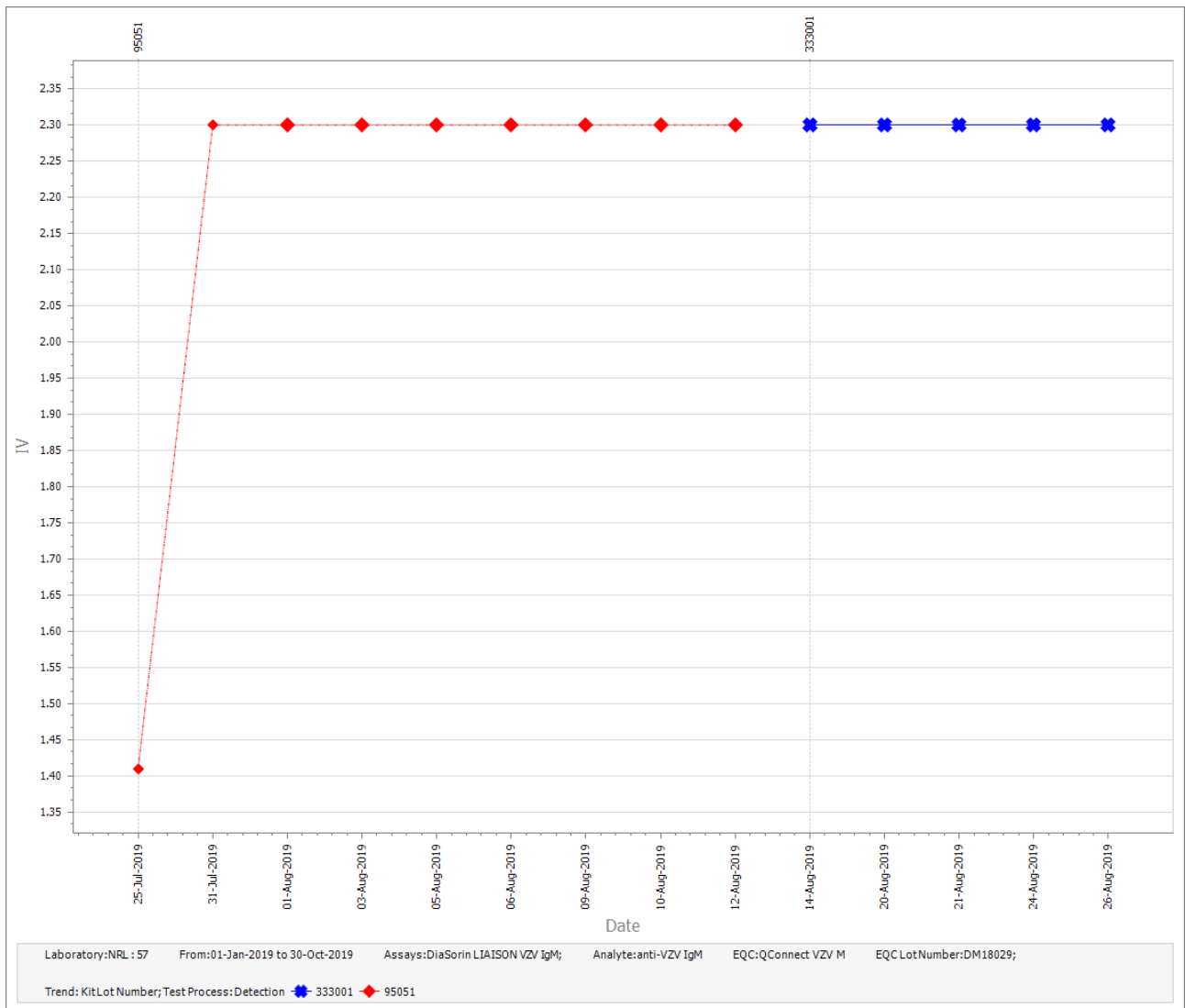


Figure 11: Participant 57 data DiaSorin LIAISON VZV IgM, QConnect VZV M DM18029.



Figure 12: Participant 57 data (red) for Roche Elecsys Anti-HAV, QConnect HEP R DM17216 in comparison with peer group data by participant.

Laboratory	n	Mean	SD	$\bar{x}-2SD$	$\bar{x}+2SD$	Min	Max	CV(%)
NRL : 57	7	27.44	NA	NA	NA	26.80	27.90	NA
NRL : 417	227	25.69	1.93	21.83	29.55	20.45	30.29	7.52
Totals	234	25.74	1.93	21.89	29.59	20.45	30.29	7.48

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys Anti-HAV;
 Analyte: anti-HAV
 EQC: QConnect HEPR
 EQC Lot Number: DM17216;

Table 3.

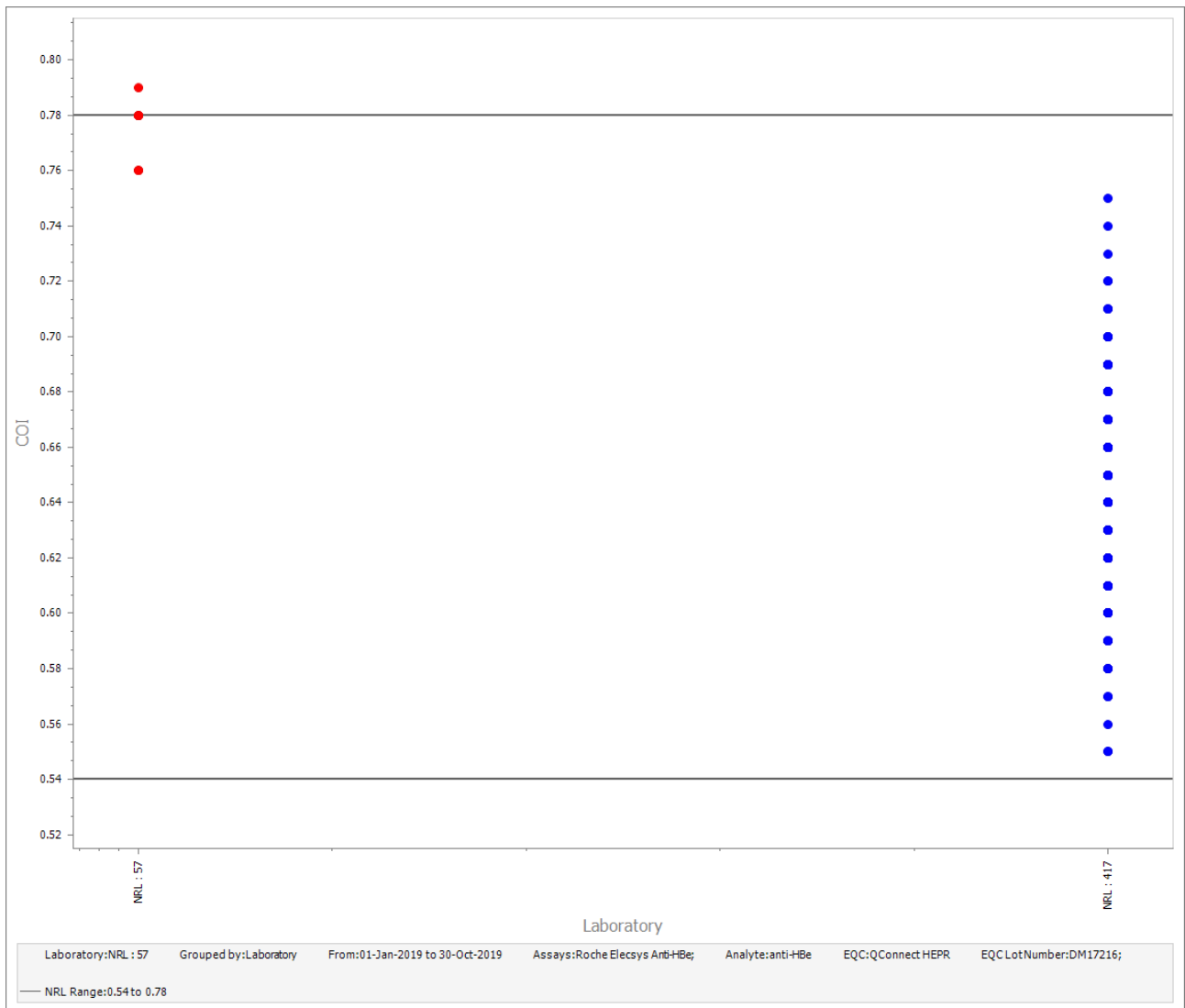


Figure 13: Participant 57 data (red) for Roche Elecsys Anti-HBe, QConnect HEP R DM17216 in comparison with peer group data by participant.



Figure 14: Participant 57 data (red) for Roche Elecsys Anti-HBe, QConnect HEP R DM17216 in comparison with peer group data by reagent lot.

Laboratory	n	Mean	SD	$\bar{x}-2SD$	$\bar{x}+2SD$	Min	Max	CV(%)
NRL : 57	6	0.77	NA	NA	NA	0.76	0.78	NA
NRL : 417	229	0.64	0.04	0.57	0.71	0.55	0.75	5.44
Totals	235	0.65	0.04	0.57	0.73	0.55	0.78	6.18

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys Anti-HBe;
 Analyte: anti-HBe
 EQC: QConnect HEPR
 EQC Lot Number: DM17216;

Table 4.

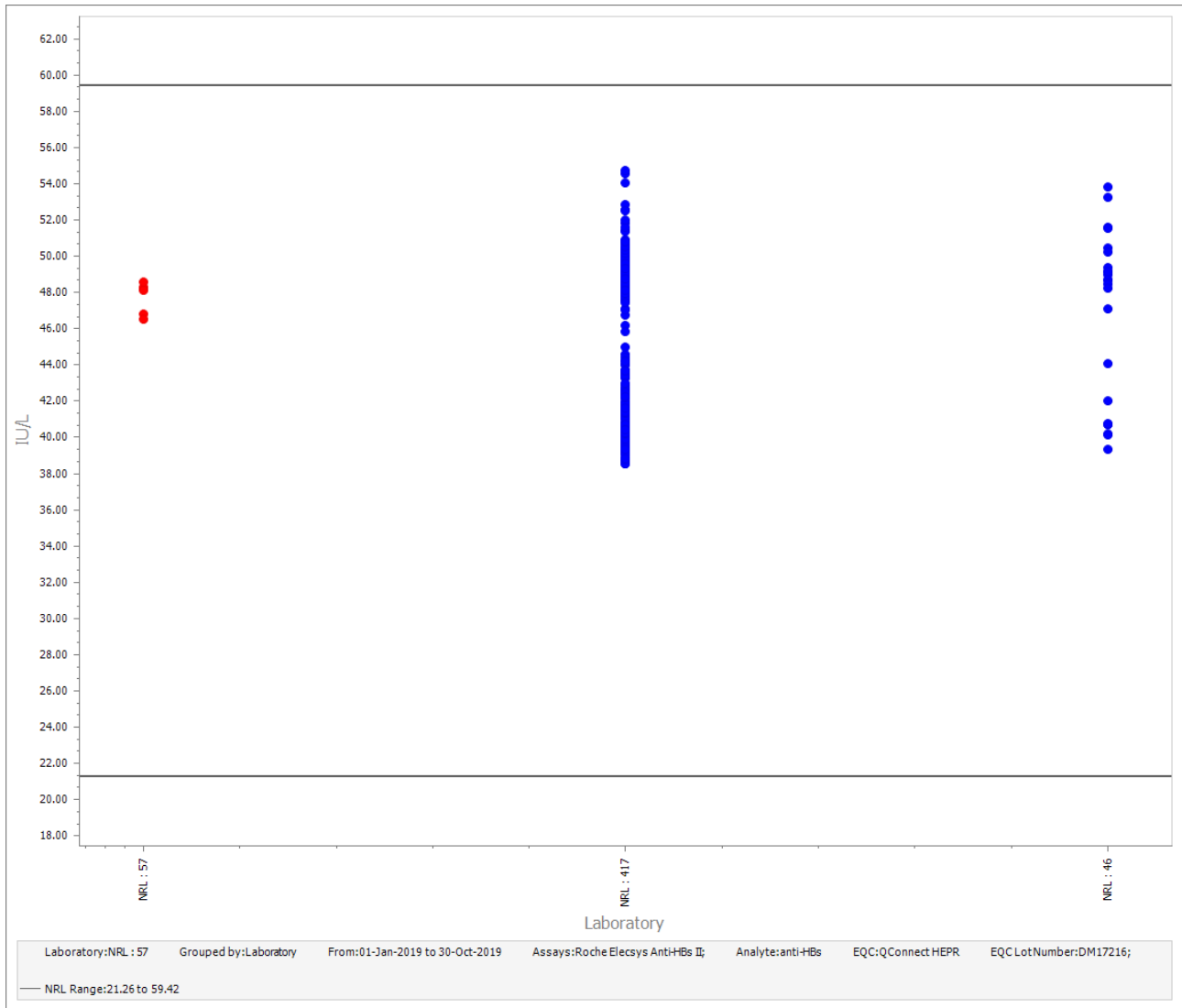


Figure 15: Participant 57 data (red) for Roche Elecsys Anti-HBs II, QConnect HEP R DM17216 in comparison with peer group data by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 57	6	47.75	NA	NA	NA	46.50	48.60	NA
NRL : 417	221	44.61	4.46	35.70	53.53	38.53	54.76	9.99
NRL : 46	23	46.82	4.68	37.47	56.17	39.35	53.82	9.99
Totals	250	44.89	4.49	35.92	53.86	38.53	54.76	9.99

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys Anti-HBs II;
 Analyte: anti-HBs
 EQC: QConnect HEPR
 EQC Lot Number: DM17216;

Table 5.

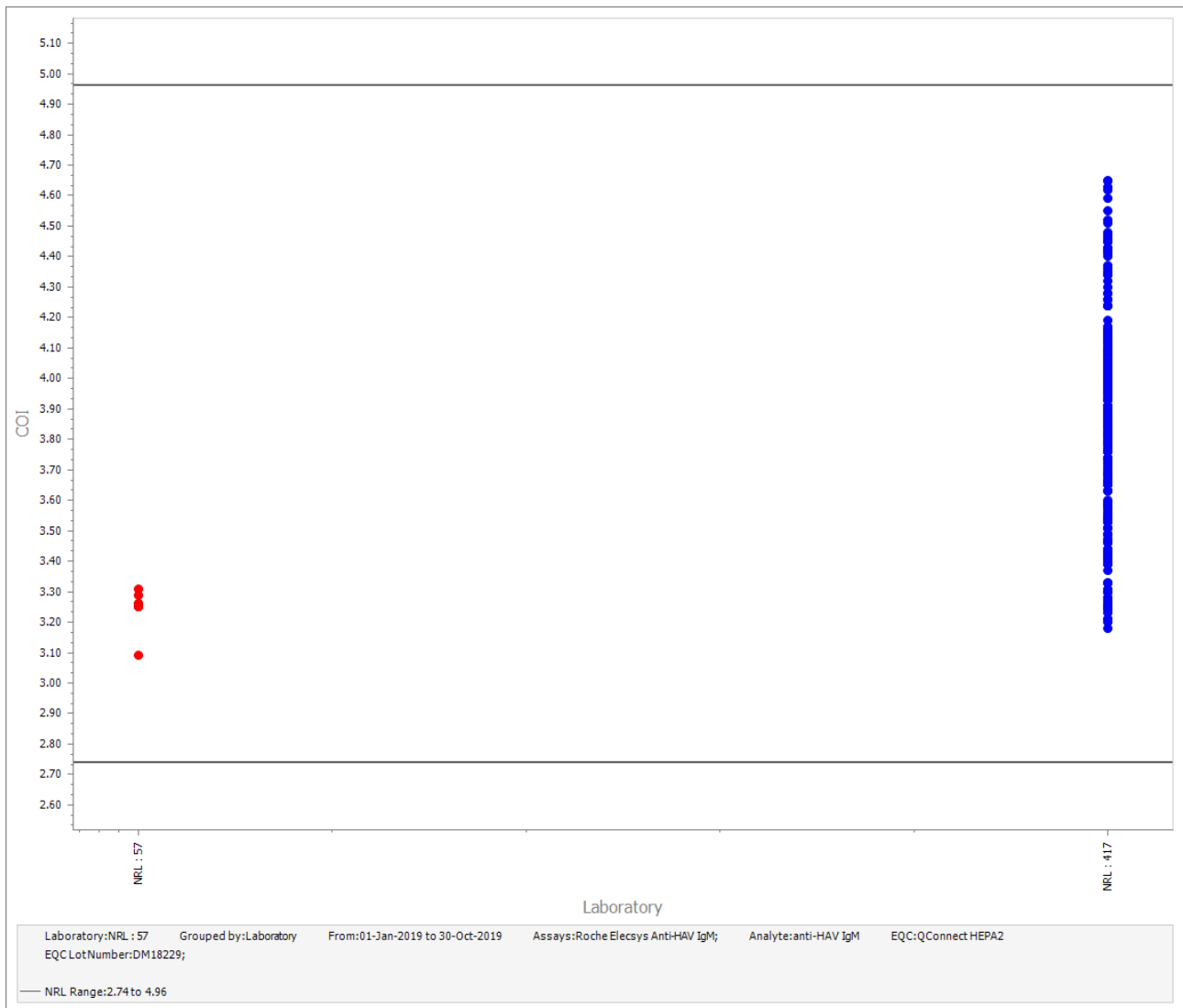


Figure 16: Participant 57 data (red) for Roche Elecsys Anti-HAV IgM, QConnect HEPA2 DM18229 in comparison with peer group data by participant.

Laboratory	n	Mean	SD	\bar{x} -2SD	\bar{x} +2SD	Min	Max	CV(%)
NRL : 57	7	3.24	NA	NA	NA	3.09	3.31	NA
NRL : 417	229	3.86	0.35	3.17	4.55	3.18	4.65	8.96
Totals	236	3.84	0.36	3.13	4.56	3.09	4.65	9.26

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys Anti-HAV IgM;
 Analyte: anti-HAV IgM
 EQC: QConnect HEPA2
 EQC Lot Number: DM18229;

Table 6.



Figure 17: Participant 57 data (red) for Roche Elecsys Anti-HBc IgM, QConnect HEPA2 DM18229 in comparison with peer group data by participant.

Laboratory	n	Mean	SD	\bar{x} -2SD	\bar{x} +2SD	Min	Max	CV(%)
NRL : 57	7	1.54	NA	NA	NA	1.46	1.60	NA
NRL : 417	212	1.90	0.25	1.40	2.40	1.43	2.80	13.15
Totals	219	1.89	0.25	1.38	2.40	1.43	2.80	13.44

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys Anti-HBc IgM;
 Analyte: IgM anti-HBc
 EQC: QConnect HEPA2
 EQC Lot Number: DM18229;

Table 7.



Figure 18: Participant 57 data (red) Roche Elecsys HBeAg, QConnect HEPA2 DM18229 in comparison with peer group data by participant.

Laboratory	n	Mean	SD	\bar{x} -2SD	\bar{x} +2SD	Min	Max	CV(%)
NRL : 57	7	2.76	NA	NA	NA	2.71	2.83	NA
NRL : 417	214	3.49	0.32	2.86	4.13	2.61	4.66	9.13
Totals	221	3.47	0.34	2.79	4.15	2.61	4.66	9.77

Legend:

Laboratory: NRL : 57
 Grouped by: Laboratory
 From: 01-Jan-2019 to 30-Oct-2019
 Assays: Roche Elecsys HBeAg;
 Analyte: HBeAg
 EQC: QConnect HEPA2
 EQC Lot Number: DM18229;

Table 8.