



QC SERVICES INVESTIGATION PMM-QC-1878

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INTRODUCTION

During routine review of data reported to EDCNet, NRL observed a shift up in S/Co values for Optitrol HEPR-2 DM24038 when tested with the Abbott Alinity i HAV Ab IgG assay. NRL investigated the performance of Optitrol HEPR-2 DM24038 and other related production lots, DM23002 and DM23080, as well as the performance of Optitrol HEPR-2 DM24038 when used with the Abbott and other assays and platforms the EQC had been designed for.

FINDINGS

This investigation looked at all assays that Optitrol HEPR-2 is recommended for, to establish whether the QC was the source of the variation observed and whether this variation was observed across any other peer group. Data from 01 January through to 28 June 2024 were reviewed for this investigation. The following are a full listing of charts and tables included in the investigation:

- Figure 1 – Participant 8 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.
- Figure 2 – Participant 40 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.
- Figure 3 – Participant 129 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.
- Figure 4 – Participant 1015 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.
- Figure 5 – Participant 1321 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.
- Figure 6 – Peer group data for Optitrol HEPR-2 when tested with Abbott Alinity i HAV Ab IgG sorted by participant.
- Figure 7 – Participant 8 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.
- Figure 8 – Participant 40 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.
- Figure 9 – Participant 129 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.
- Figure 10 – Participant 1015 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.
- Figure 11 – Participant 1321 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.
- Figure 12 – Peer group data for Optitrol HEPR-2 when tested with Abbott Alinity i Anti-HBs sorted by participant.
- Figure 13 – Participant 36 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT HAVAb IgG.
- Figure 14 – Participant 43 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT HAVAb IgG.
- Figure 15 – Participant 128 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT HAVAb IgG.
- Figure 16 – Peer group data for Optitrol HEPR-2 when tested with Abbott ARCHITECT HAVAb IgG sorted by participant.
- Figure 17 – Participant 36 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.
- Figure 18 – Participant 43 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.
- Figure 19 – Participant 128 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.
- Figure 20 – Peer group data for Optitrol HEPR-2 when tested with Abbott ARCHITECT Anti-HBs sorted by participant.

- Figure 21 – Participant 417 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Roche Elecsys Anti-HAV II.
- Figure 22 – Peer group data for Optitrol HEPR-2 when tested with Roche Elecsys Anti-HAV II sorted by participant.
- Figure 23 – Participant 417 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Roche Elecsys Anti-HBs II.
- Figure 24 – Peer group data for Optitrol HEPR-2 when tested with Roche Elecsys Anti-HBs II sorted by participant.
- Table 1 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i HAV Ab IgG viewed by participant.
- Table 2 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott Alinity i HAV Ab IgG viewed by participant.
- Table 3 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i Anti-HBs viewed by participant.
- Table 4 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott ARCHITECT HAVAb IgG viewed by participant.
- Table 5 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i Anti-HBs viewed by participant.
- Table 6 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott ARCHITECT HAVAb IgG viewed by participant.
- Table 7 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott ARCHITECT Anti-HBs viewed by participant.
- Table 8 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott ARCHITECT Anti-HBs viewed by participant.
- Table 9 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Roche Elecsys Anti-HAV II viewed by participant.
- Table 10 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Roche Elecsys Anti-HAV II viewed by participant.
- Table 11 – Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Roche Elecsys Anti-HBs II viewed by participant.
- Table 12 – Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Roche Elecsys Anti-HBs II viewed by participant.

DISCUSSION

Figures 1 to 24 show data for participants (both individual and peer group performance) that demonstrates a shift in reported unit of measure for analytes anti-HAV and anti-HBs for Optitrol HEPR-2 lot DM24038, when tested with Abbott Alinity i HAV Ab IgG, Abbott Alinity i Anti-HBs, Abbott ARCHITECT HAVAb IgG, Abbott ARCHITECT Anti-HBs, Roche Elecsys Anti-HAV II and Elecsys Anti-HBs II assays. All assays, except the Roche Elecsys Anti-HAV II, showed a shift up in up in values. The Roche Elecsys Anti-HAV II assay showed a consistent degree of shift; however, data were reported at a lower value inconsistent with other Anti-HAV assays investigated. No shift in data was observed for the anti-HBe assays for the investigated platforms.

Figures 1 to 5 show data for participants reporting data for Optitrol HEPR-2 lot DM24038 when testing with the Abbott Alinity i HAV Ab IgG assay. A total of three reagent lots were in use across the peer group for both HEPR-2 DM24038 and previous HEPR-2 lots. Tables 1 and 2 show peer group data for these reagent lots illustrating a mean S/Co value of 2.44 for Optitrol HEPR-2 DM23080 and 3.98 for Optitrol HEPR-2 DM24038. This shift up was observed for all participants with reported data for Optitrol HEPR-2 DM24038.

Figure 5 shows data for Participant 1321, illustrating the higher S/Co values reported for HEPR-2 DM24038 on reagent lot 57170BE00 are also observed for reagent lot 6040BE00.

This was the only participant reporting data for reagent lot 6040BE00, no data were reported for previous HEPR-2 lots for this reagent lot.

Figures 7 to 11 show data for participants reporting data for Optitrol HEPR-2 lot DM24038 when testing with the Abbott Alinity i Anti-HBs assay. A total of four reagent lots were in use across the peer group for both HEPR-2 DM24038 and previous HEPR-2 lots. Tables 3 and 4 show peer group data for these reagent lots illustrating a mean mIU/mL value of 23.67 for Optitrol HEPR-2 DM23080 and 31.84 for Optitrol HEPR-2 DM24038. This shift up was observed for all participants with reported data for Optitrol HEPR-2 DM24038.

Figures 9 and 11, show data Participants 129 and 1321, illustrating multiple shifts in data with the ongoing use of both Optitrol HEPR-2 DM23080 and DM24038 for reagent lots 58538FN00 and 58636FN00.

Figure 10, Participant 1015, illustrates a shift up in data reported for Optitrol HEPR-2 DM23080 / 55282FN00. This shift was the subject of another investigation (PMM-QC-1753) and thus was unrelated to this investigation.

Figures 13 to 15 show data for participants reporting data for Optitrol HEPR-2 lot DM24038 when testing with the Abbott ARCHITECT HAVAb – IgG assay. A total of three reagent lots were in use across the peer group for both HEPR-2 DM24038 and previous HEPR-2 lots. Tables 5 and 6 show peer group data for these reagent lots illustrating a mean S/Co value of 2.26 for Optitrol HEPR-2 DM23080 and 3.57 for Optitrol HEPR-2 DM24038. This shift up was observed for all participants that reported data for Optitrol HEPR-2 DM24038.

Figures 17 to 19 show data for participants reporting data for Optitrol HEPR-2 lot DM24038 when testing with the Abbott ARCHITECT Anti-HBs assay. A total of four reagent lots were in use across the peer group for both HEPR-2 DM24038 and previous HEPR-2 lots. Tables 7 and 8 show peer group data for these reagent lots illustrating a mean mIU/mL value of 24.36 for Optitrol HEPR-2 DM23080 and 32.31 for Optitrol HEPR-2 DM24038. This shift up was observed for all participants with reported data for Optitrol HEPR-2 DM24038.

Figure 21 shows data for Participant 417 reporting data for Optitrol HEPR-2 lot DM24038 when testing with the Roche Elecsys Anti-HAV II assay. Participant 417 reported data for two reagent lots with data reported across several Optitrol HEPR-2 lots including DM24038. Tables 9 and 10 show peer group data for these reagent lots illustrating a mean COI value of 0.40 for Optitrol HEPR-2 DM23080 and 0.29 for Optitrol HEPR-2 DM24038.

The Roche Elecsys Anti-HAV II assay is a competitive assay resulting in a shift down in COI value observed equating to the shift up for other Anti-HAV assays investigated.

Figure 23 shows data reported by Participant 417 for Optitrol HEPR-2 lot DM24038 when testing with the Roche Elecsys Anti-HBs II assay. Participant 417 reported data for one reagent lot with data reported for both HEPR-2 DM24038 and previous HEPR-2 lots. Tables 11 and 12 show peer group data for these reagent lots illustrating a mean IU/L value of 37.16 for Optitrol HEPR-2 DM23080 and 49.38 for Optitrol HEPR-2 DM24038. This shift up is consistent with the shift noted on previously investigated platforms and assays.

The shift in data observed for Optitrol HEPR-2 DM24038 on the investigated assays has resulted in data falling outside QConnect limits as set for previous Optitrol HEPR-2 lots requiring individual limits to be calculated.

NRL contacted DiaMex, requesting information on all manufacturing or material changes

made in the manufacturing of Optitrol HEPR-2 DM24038 in comparison to previous Optitrol HEPR-2 lots. DiaMex communicated to NRL that HEPR-2 lots, DM23002, DM23080 and DM24038 were all manufactured using the same positive stock material and at the same concentration.

For the peer groups where Kit control data was reported to EDCNet no shift or similar variation was observed.

NRL reviewed and discussed the findings of this investigation with DiaMex. DiaMex confirmed again that no manufacturing changes had occurred in the preparation or production of Optitrol HEPR-2 lot DM24038. DiaMex also provided current testing for lot release samples confirming no change evident in evaluation or lot release data results.

CONCLUSIONS

The unexpected shift in data was observed across multiple platforms and assays, in combination with data from previous Optitrol HEPR-2 lots testing as expected on the same reagent lots where the shift was observed for Optitrol HEPR-2 DM24038, leading to a requirement for further investigation to pinpoint the root cause. Results for all markers tested for Optitrol HEPR-2 lot DM24038 were all determined as acceptable according to assay interpretation.

RECOMMENDATIONS

NRL will set independent control limits for Optitrol HEPR-2 DM24038 for the assay where the shift was observed and investigated in this report.

NRL will closely review the lot release and reported peer group data for the subsequent lot of Optitrol HEPR-2, determining if this shift is likely to be an ongoing and consistent shift.

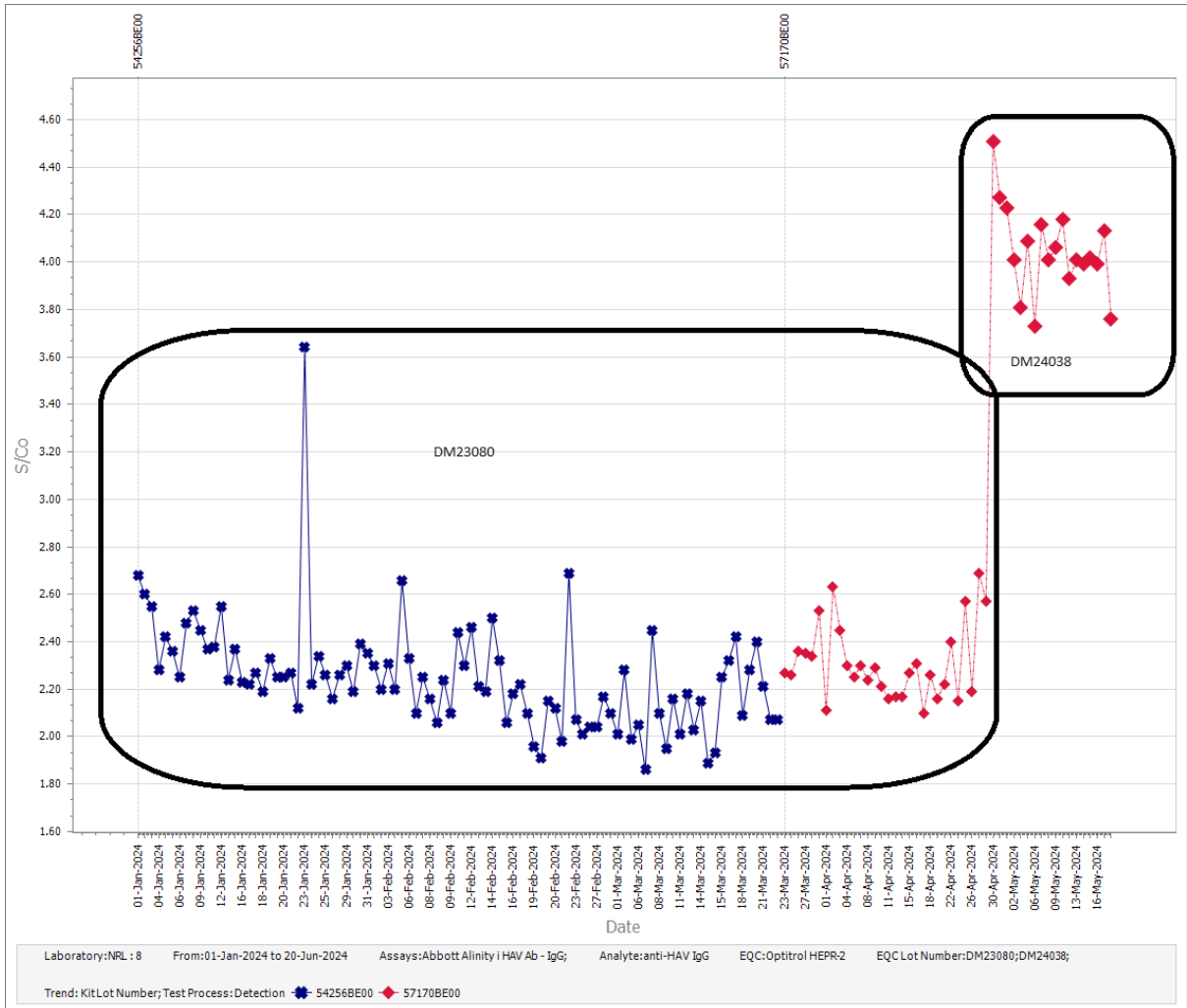


Figure 1 –Participant 8 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.

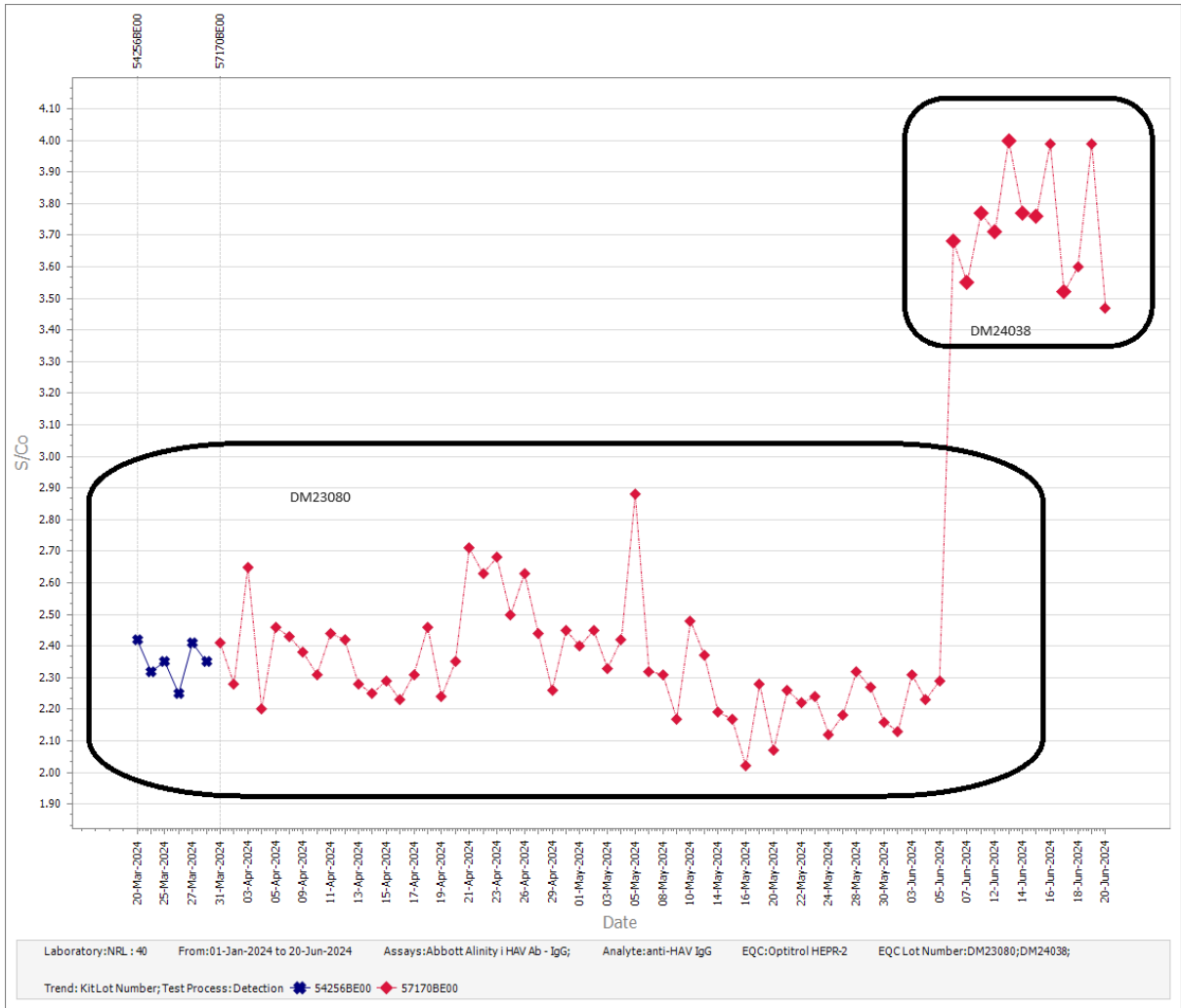


Figure 2 – Participant 40 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.

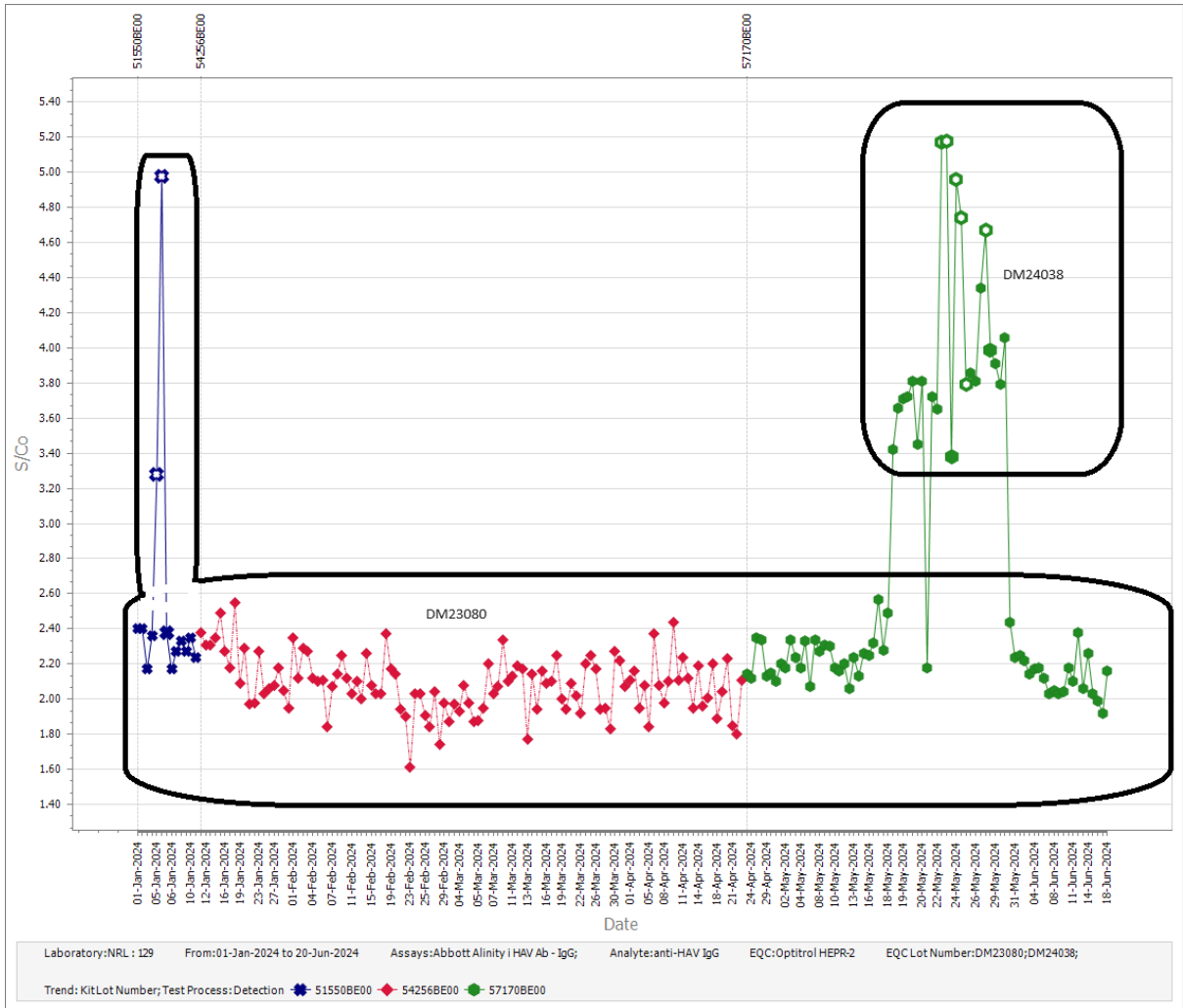


Figure 3 – Participant 129 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.

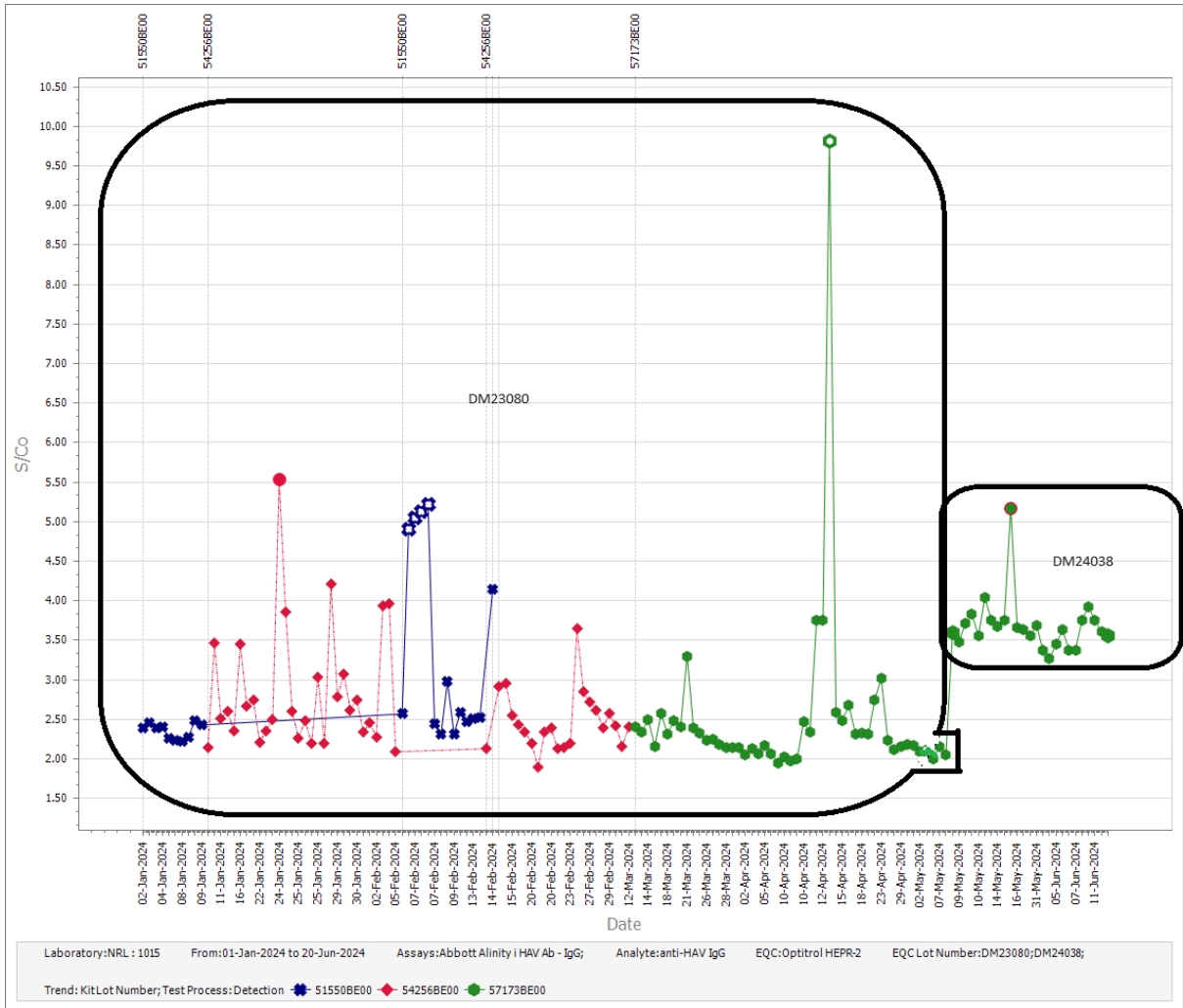


Figure 4 – Participant 1015 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.

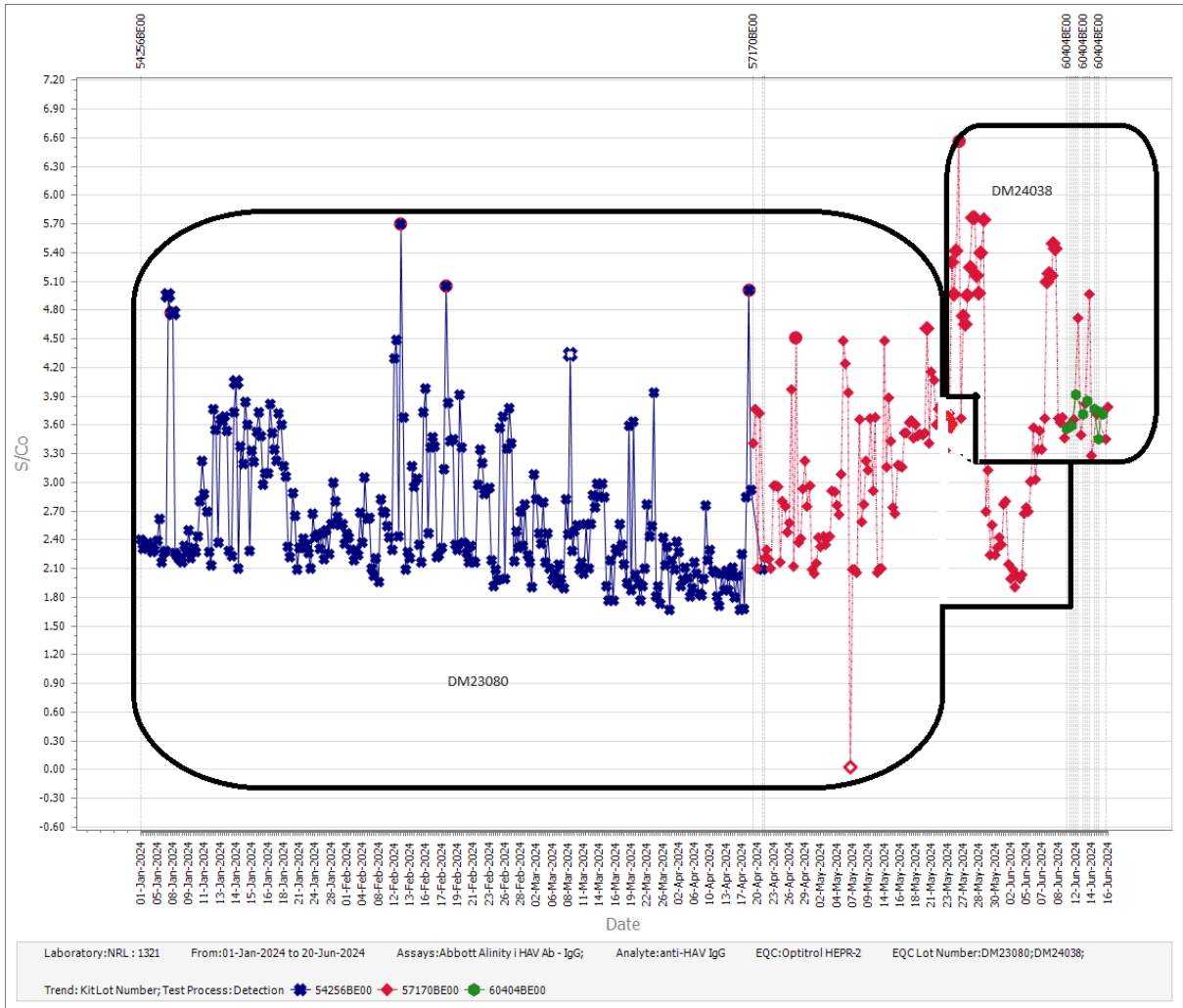


Figure 5 – Participant 1321 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i HAV Ab IgG.

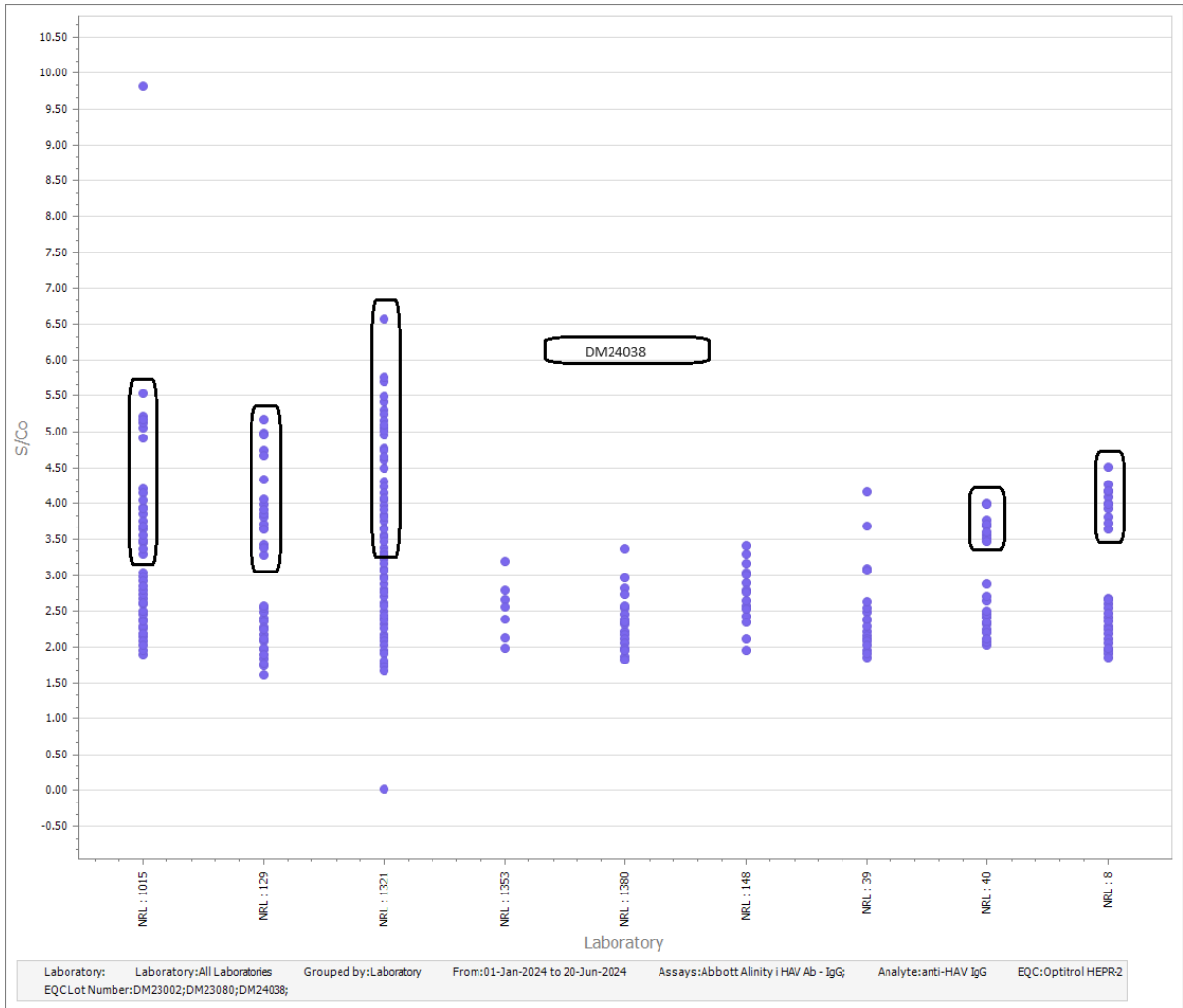


Figure 6 – Peer group data for Optitrol HEPR-2 when tested with Abbott Alinity i HAV Ab IgG sorted by participant.

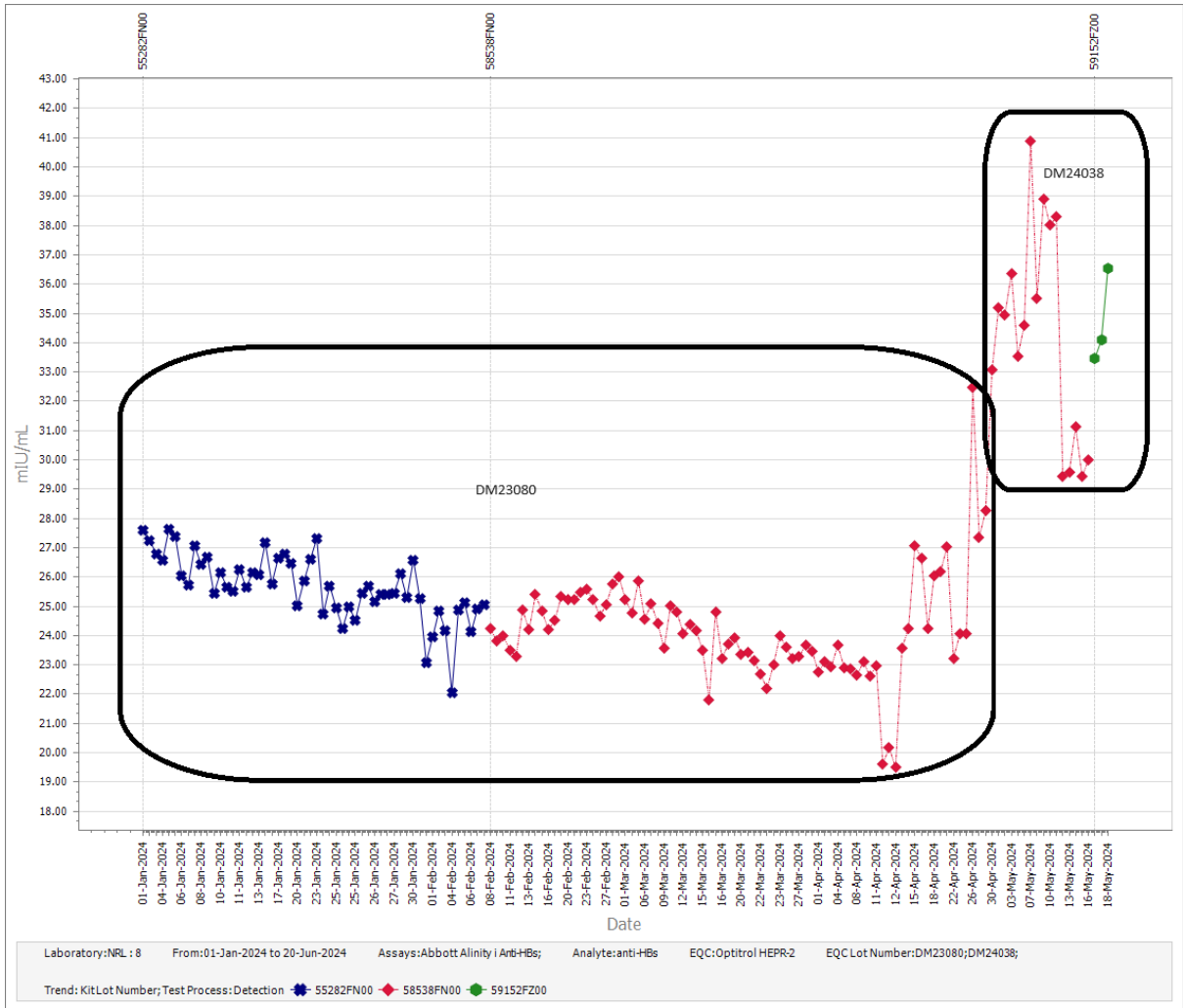


Figure 7 –Participant 8 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.

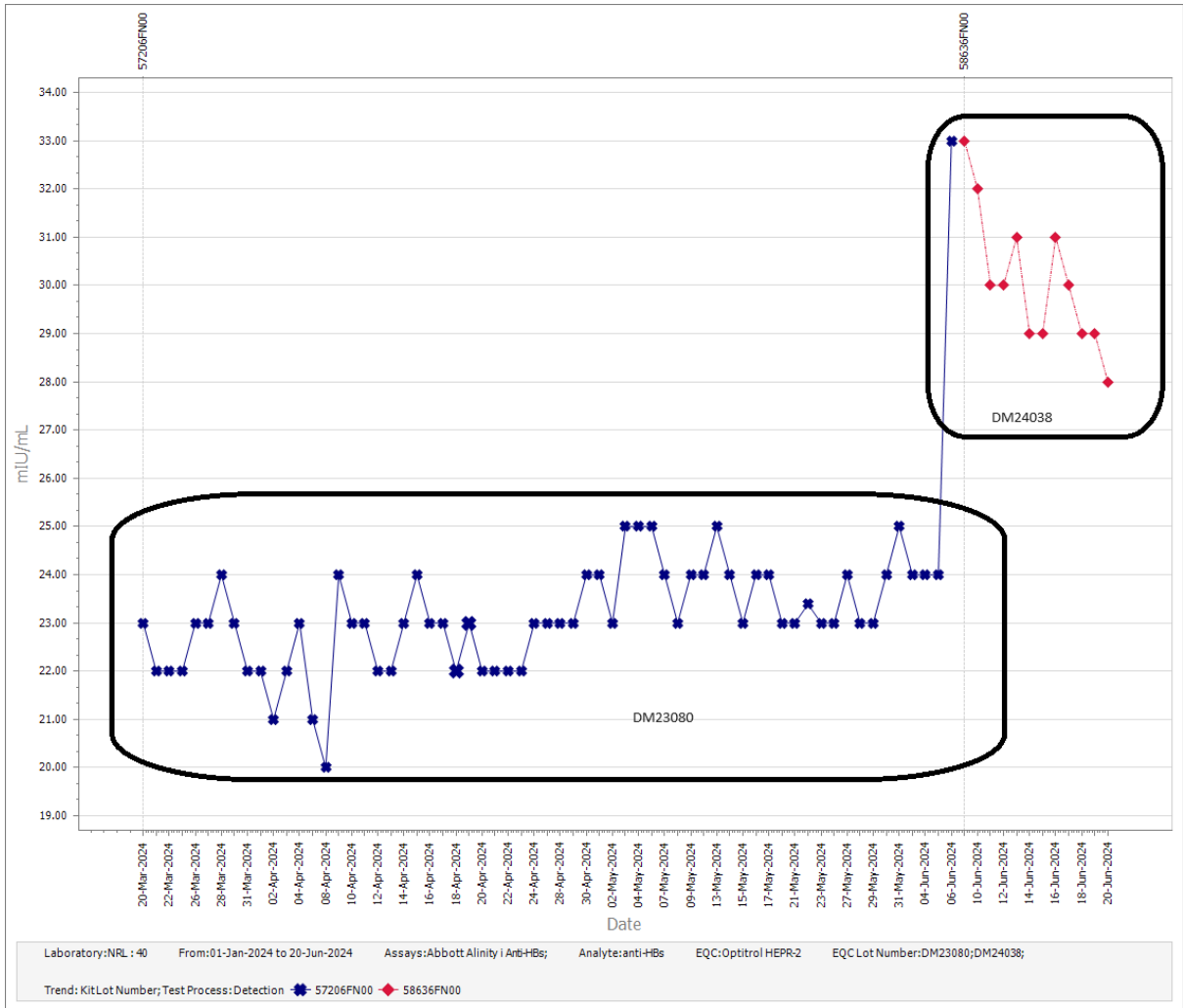


Figure 8 – Participant 40 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.

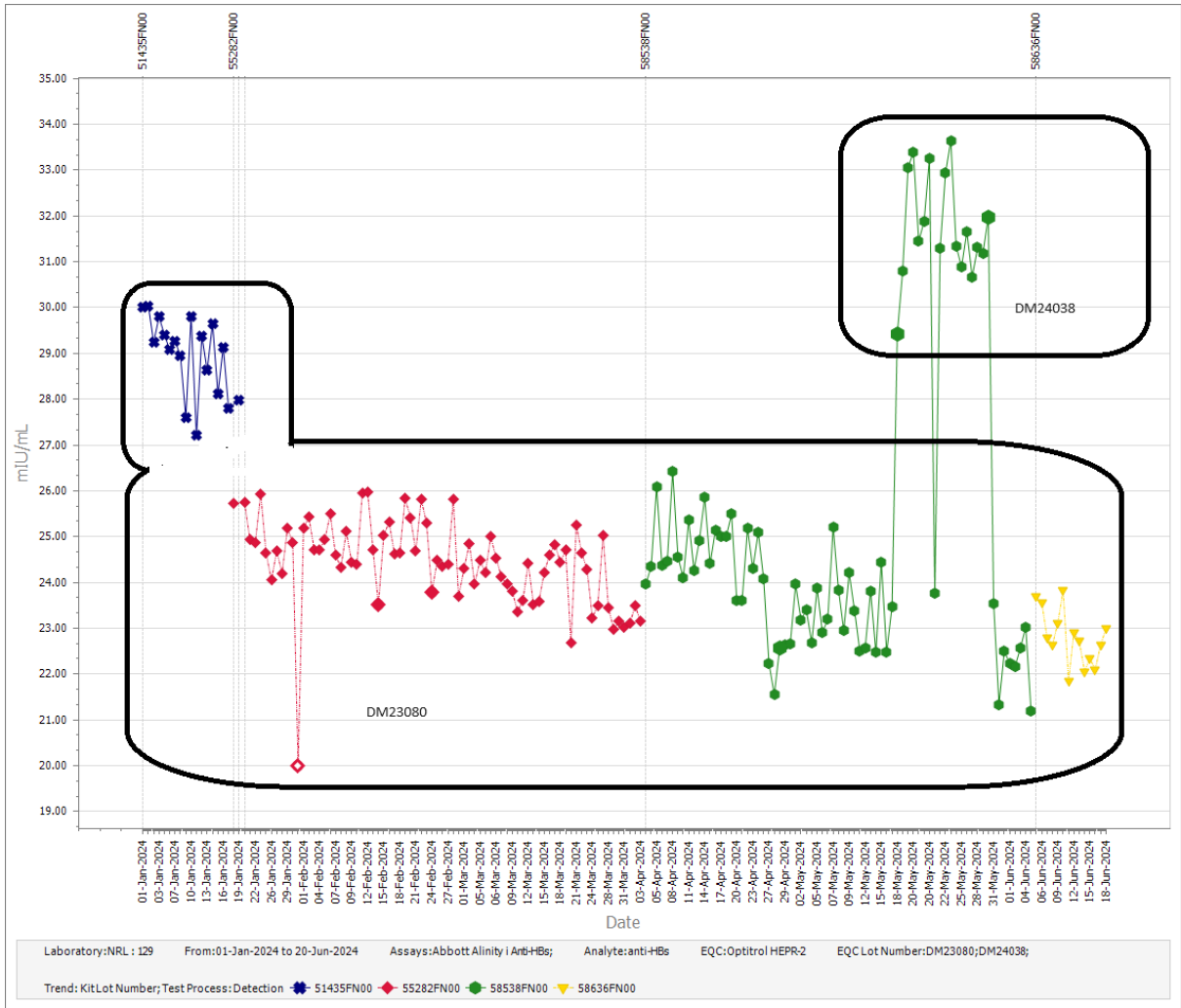


Figure 9 – Participant 129 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.

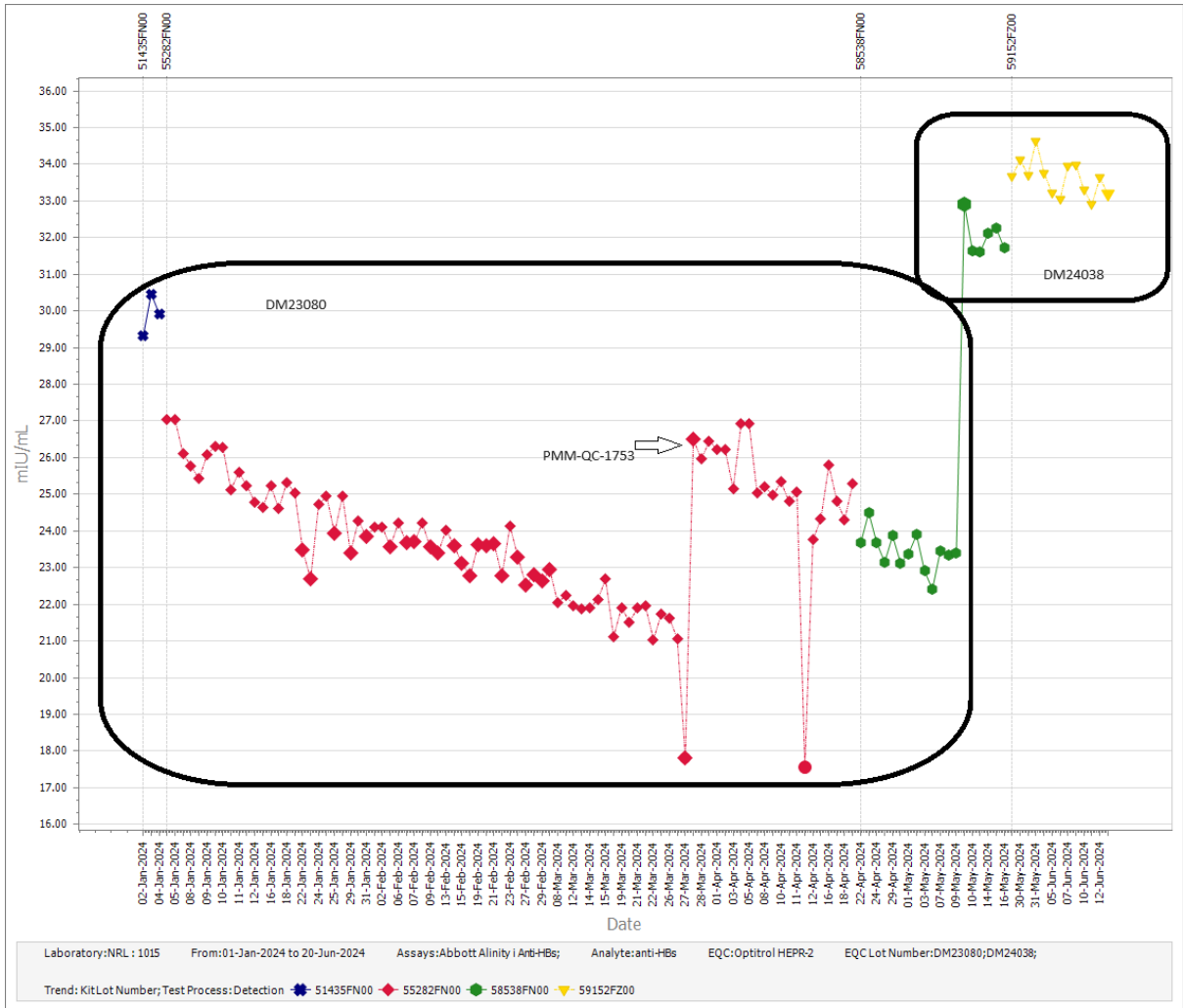


Figure 10 – Participant 1015 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.

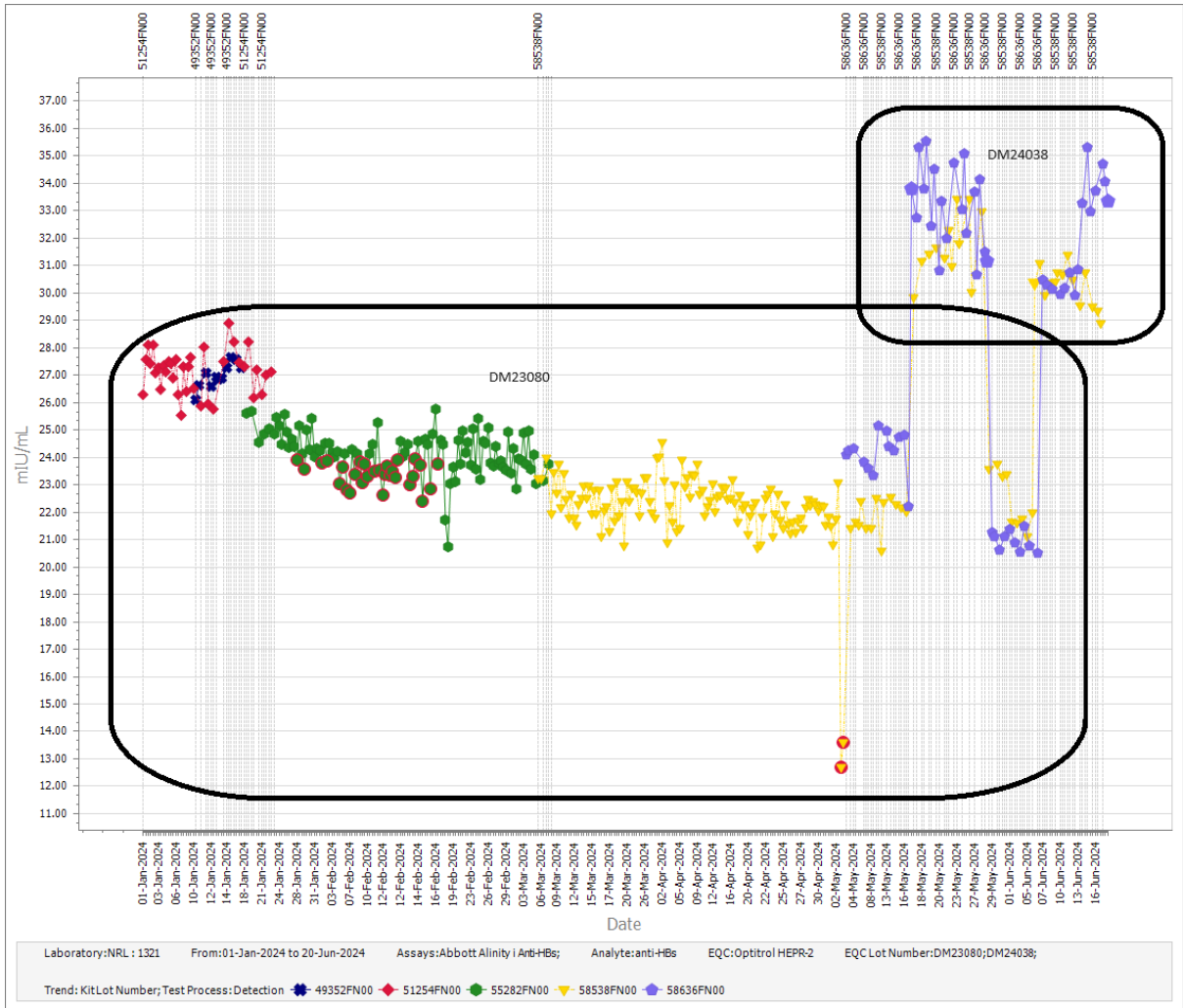


Figure 11 – Participant 1321 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott Alinity i Anti-HBs.

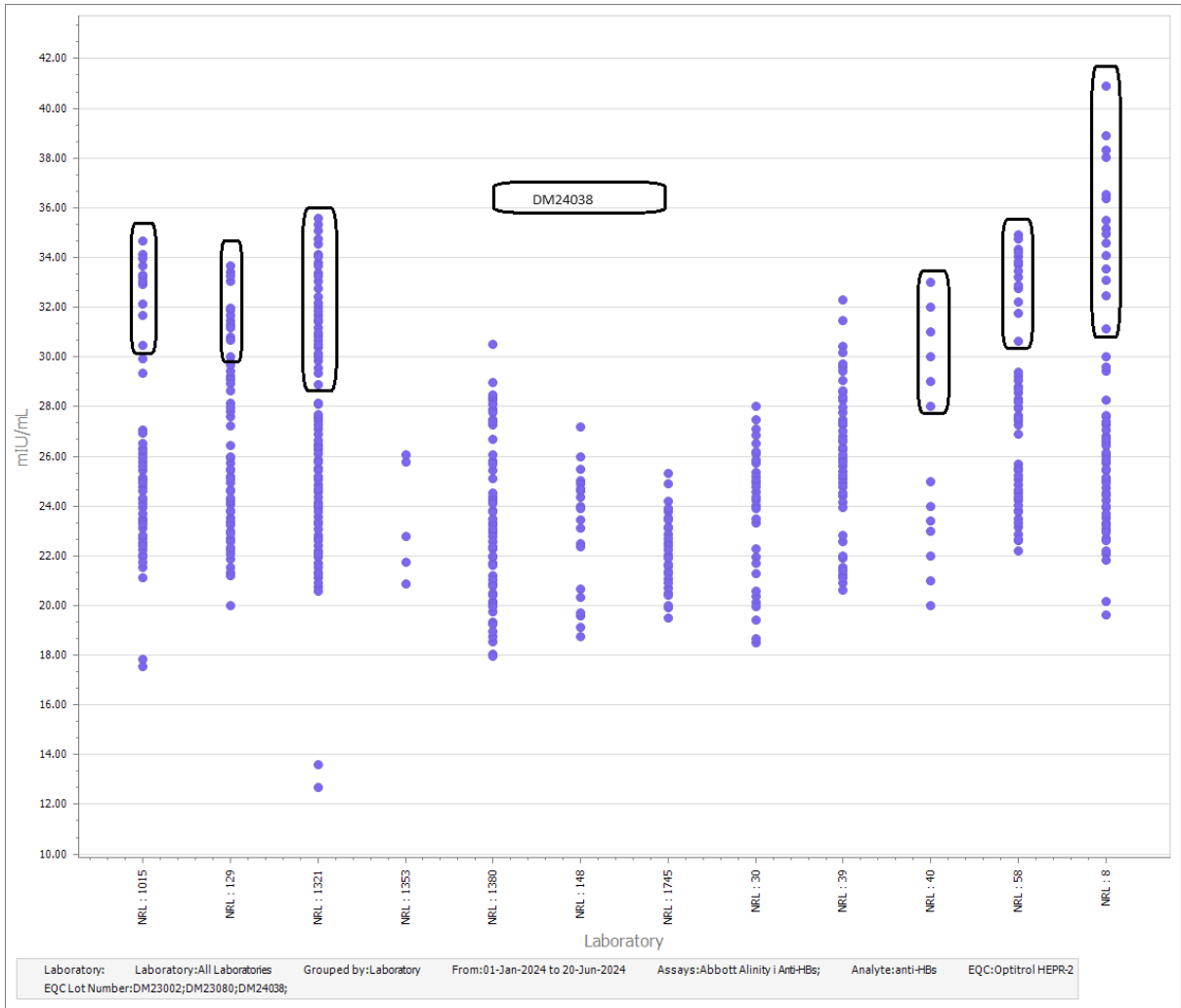


Figure 12 – Peer group data for Optitrol HEPR-2 when tested with Abbott Alinity i Anti-HBs sorted by participant.

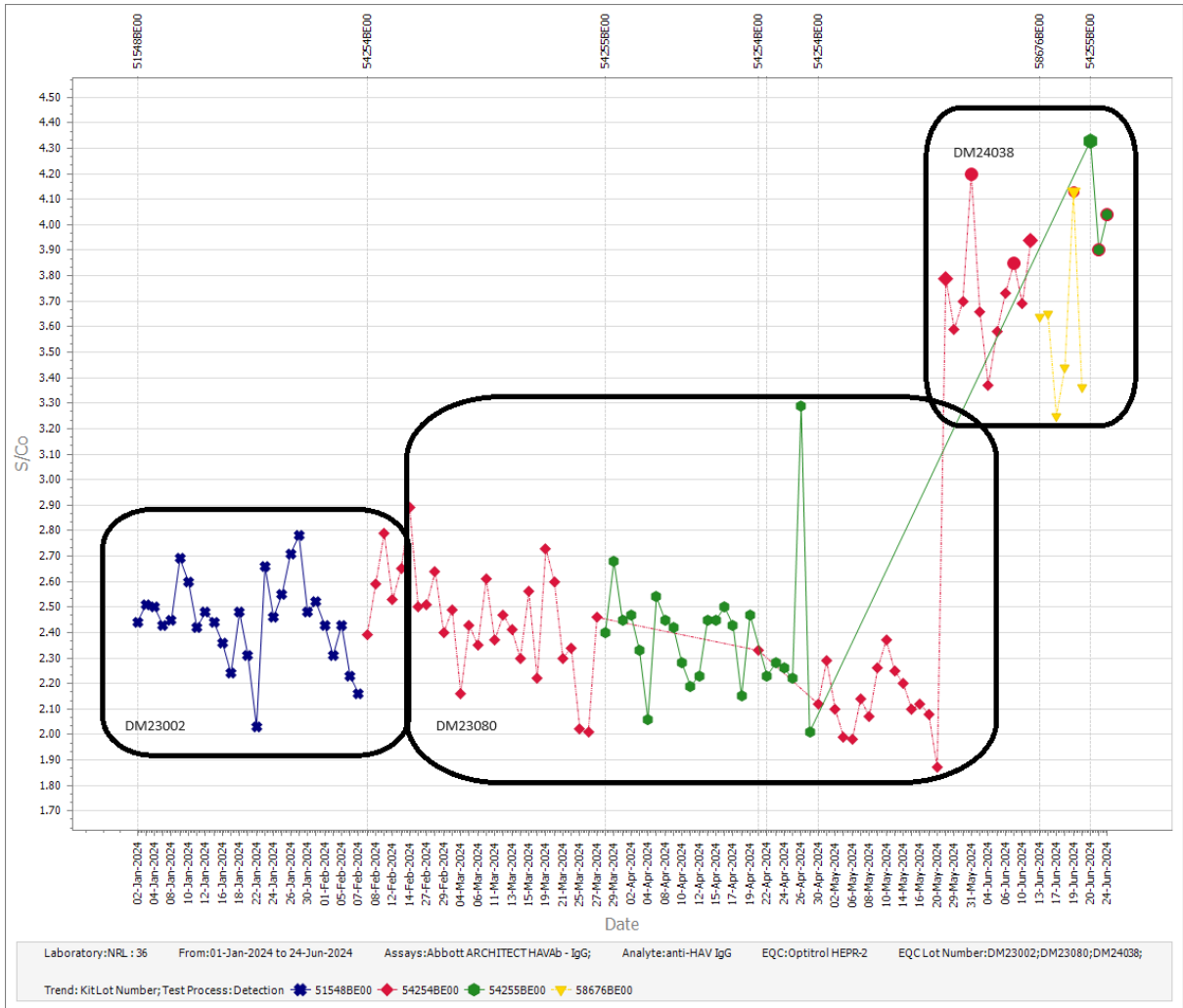


Figure 13 – Participant 36 data demonstrating shift observed for Optitrol HEP-2 DM24038 when testing with Abbott ARCHITECT HAVAb – IgG.

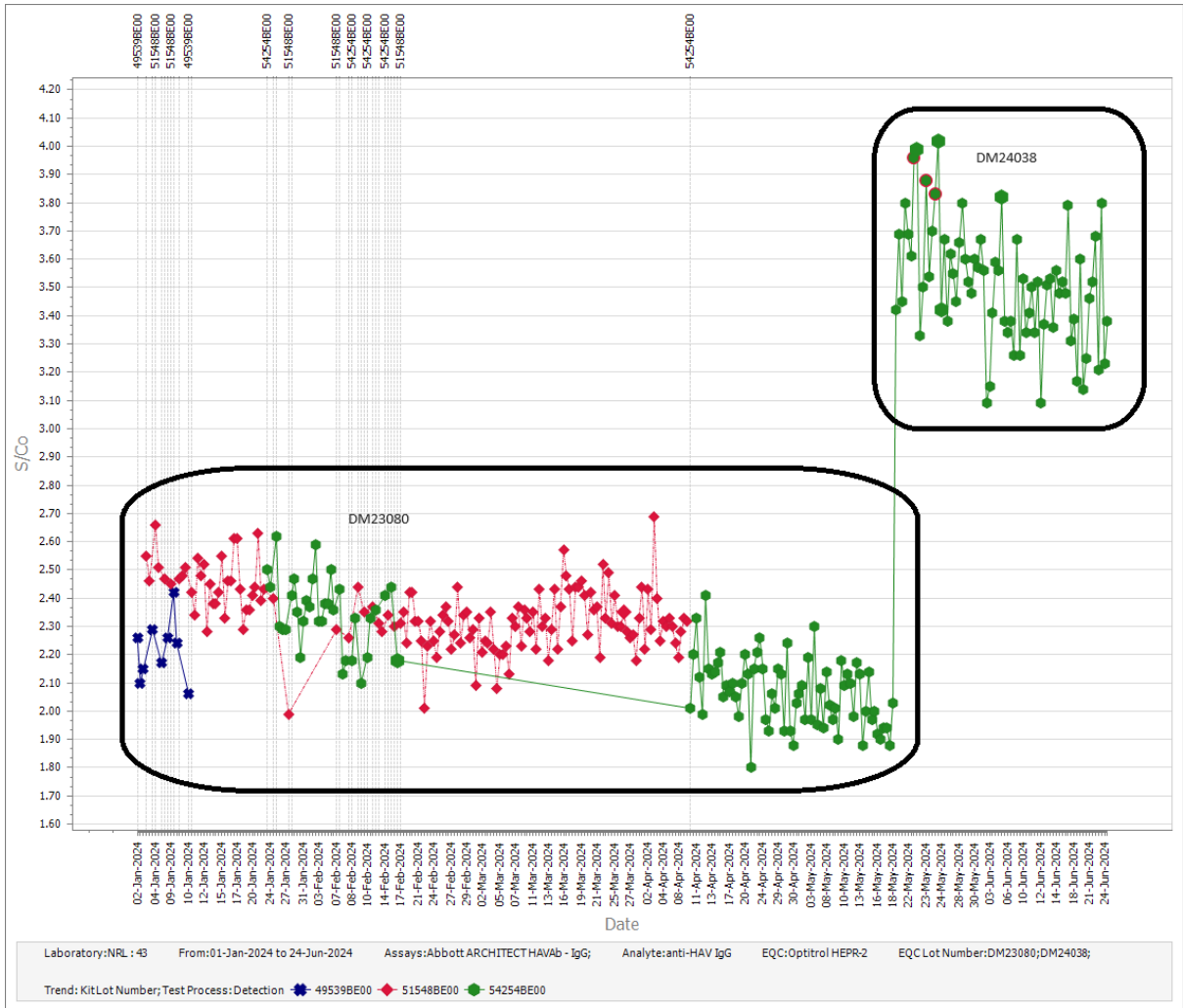


Figure 14 – Participant 43 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT HAVAb – IgG.

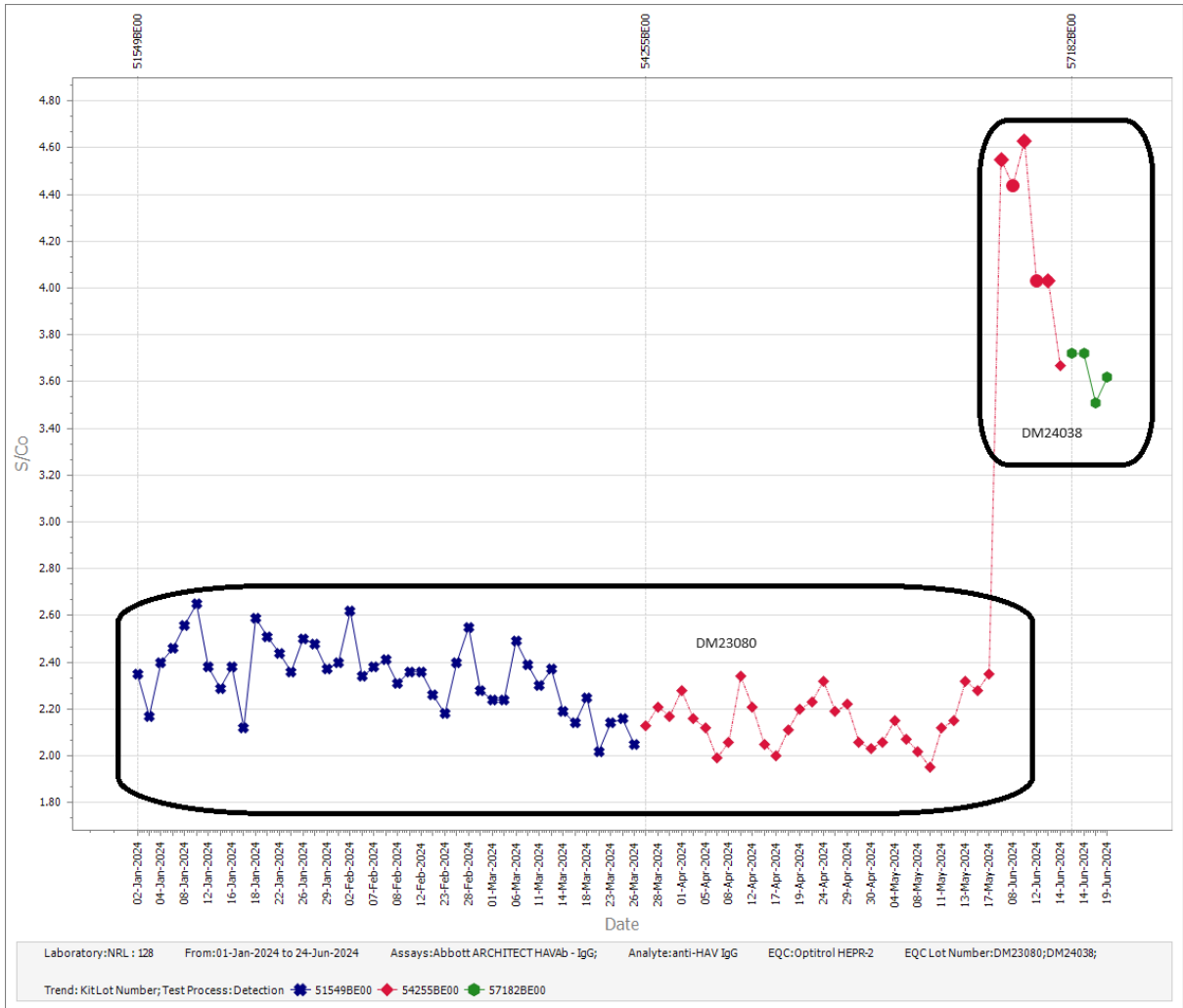


Figure 15 – Participant 128 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT HAVAb – IgG.

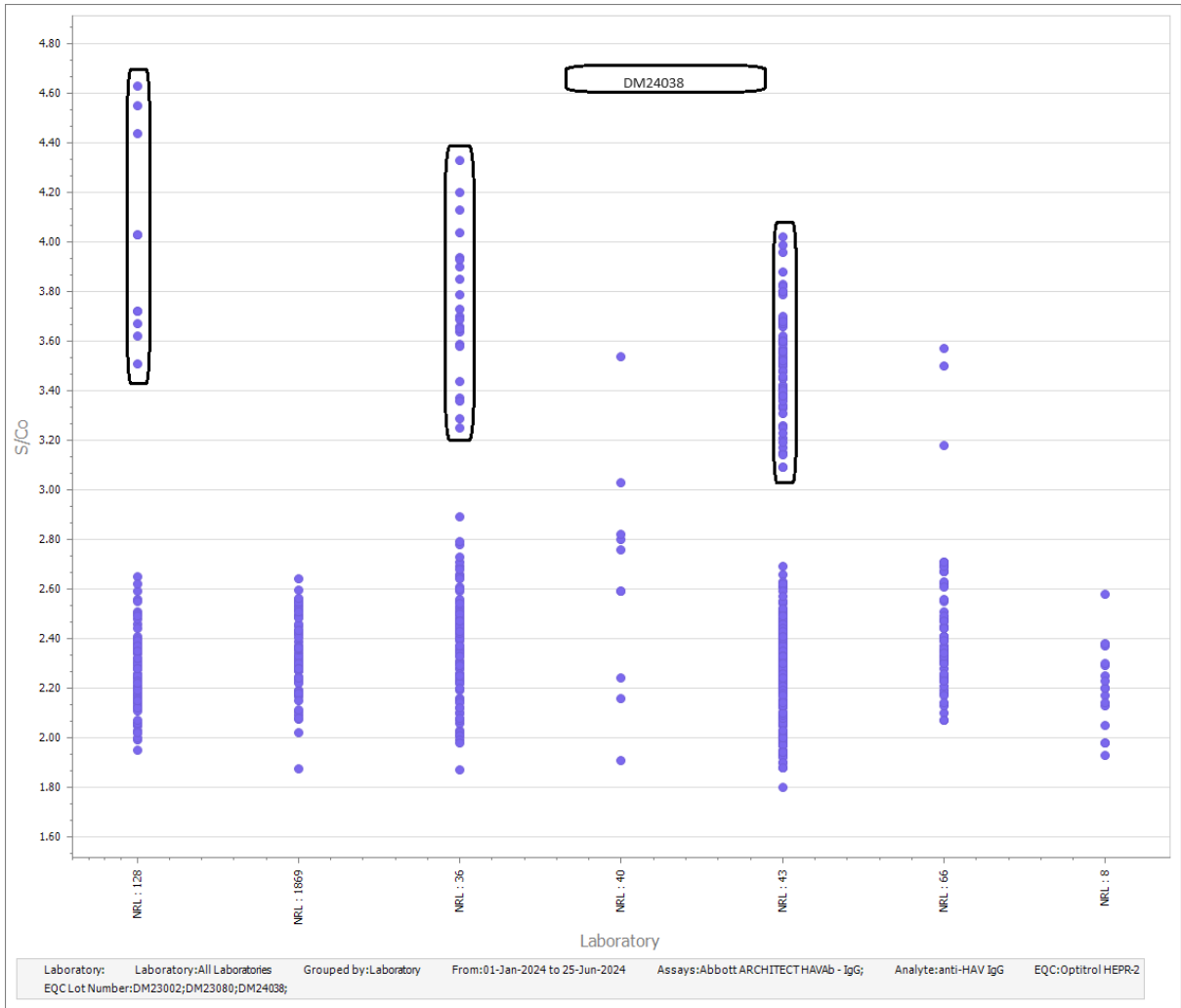


Figure 16 – Peer group data for Optitrol HEPR-2 when tested with Abbott ARCHITECT HAVAb – IgG sorted by participant.

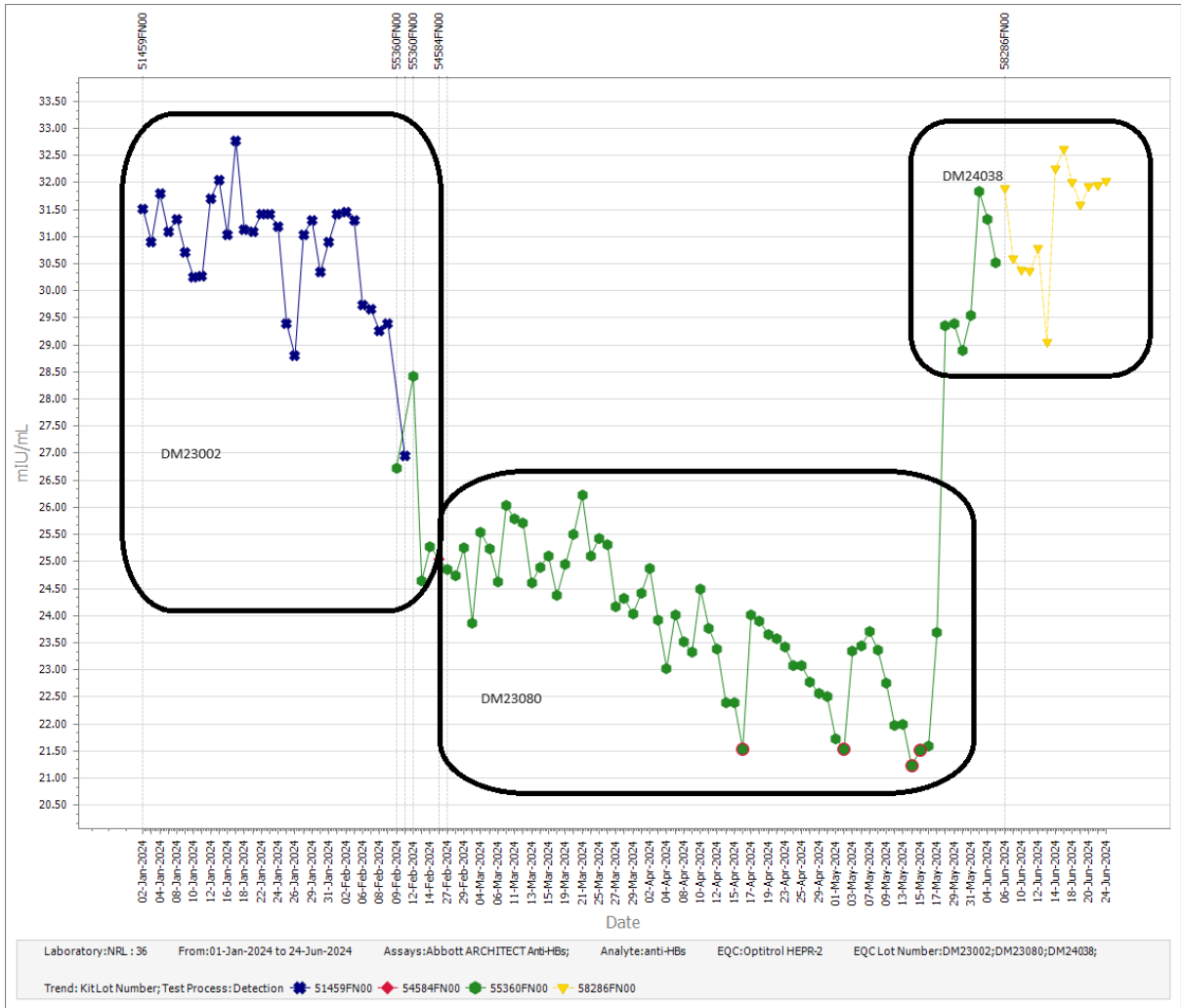


Figure 17 – Participant 36 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.

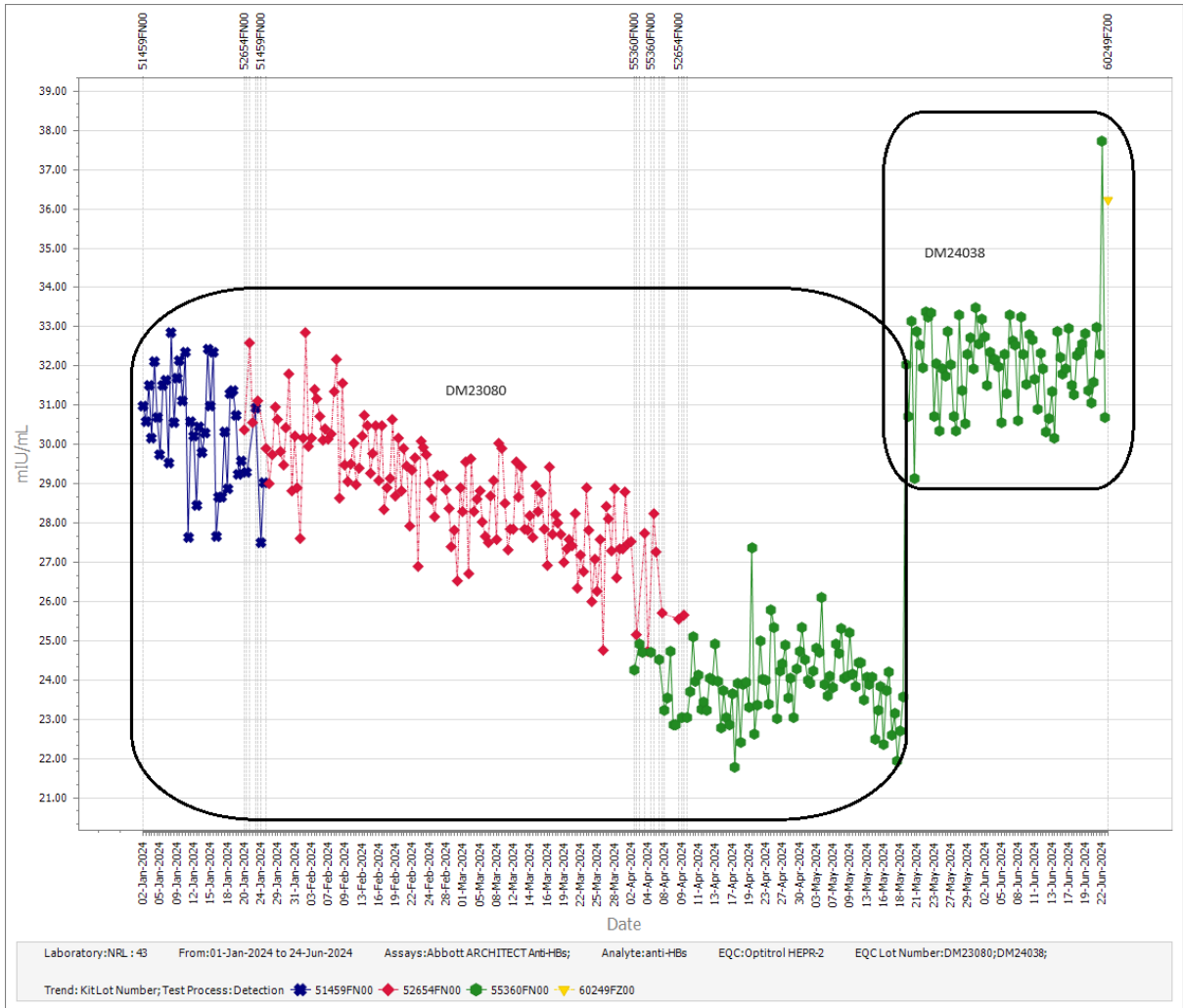


Figure 18 – Participant 43 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.

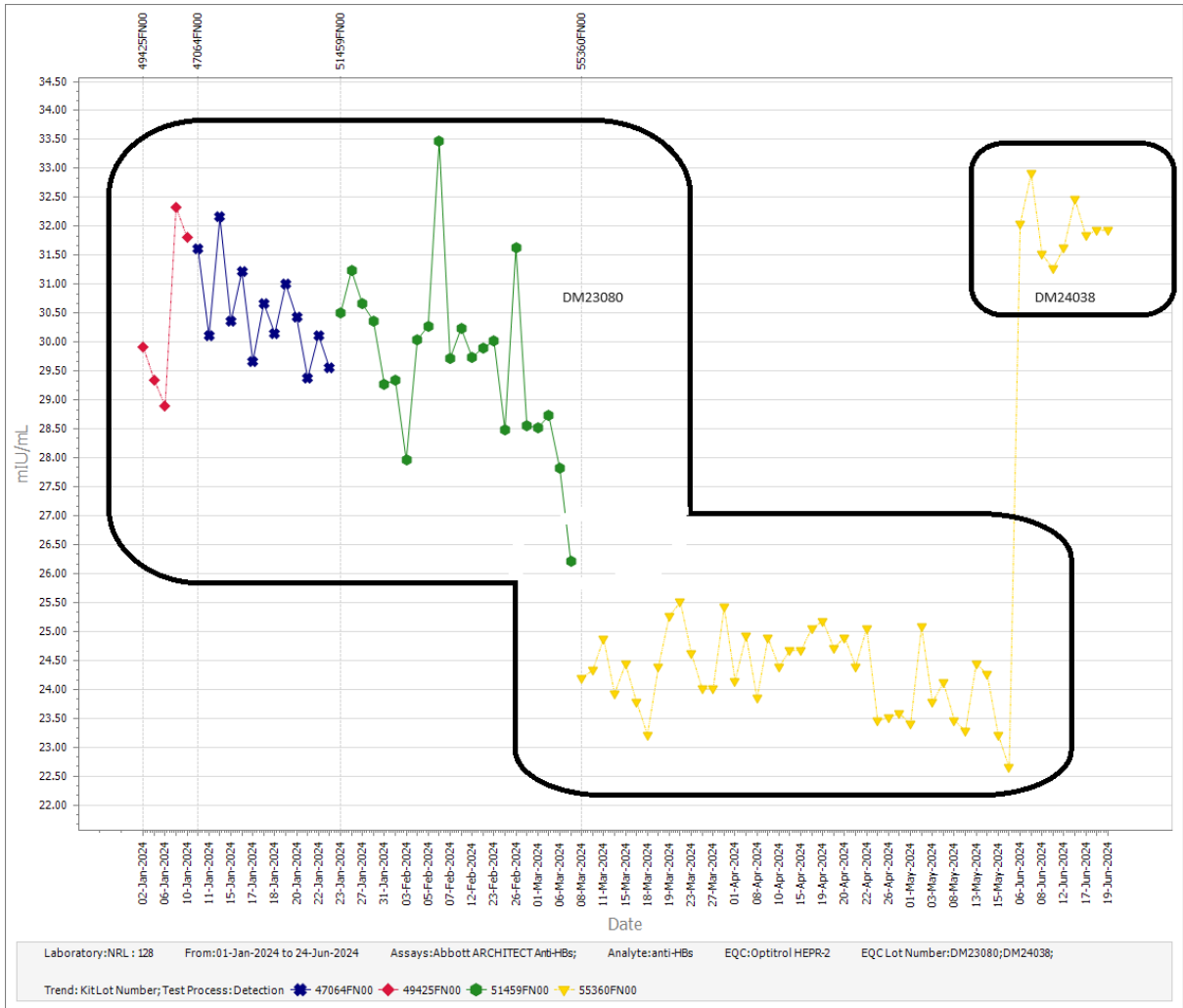


Figure 19 – Participant 128 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Abbott ARCHITECT Anti-HBs.

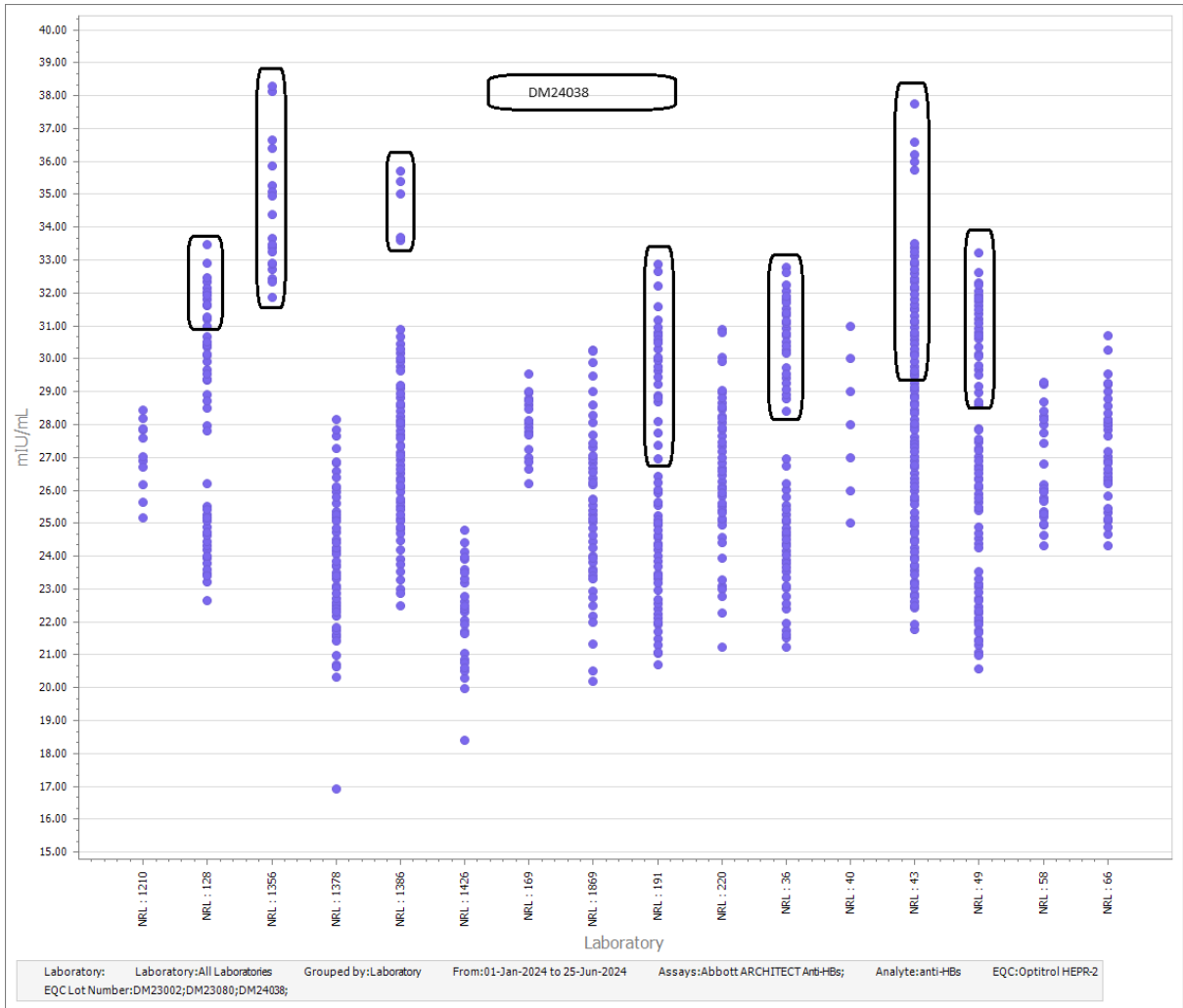


Figure 20 – Peer group data for Optitrol HEPR-2 when tested with Abbott ARCHITECT Anti-HBs sorted by participant.

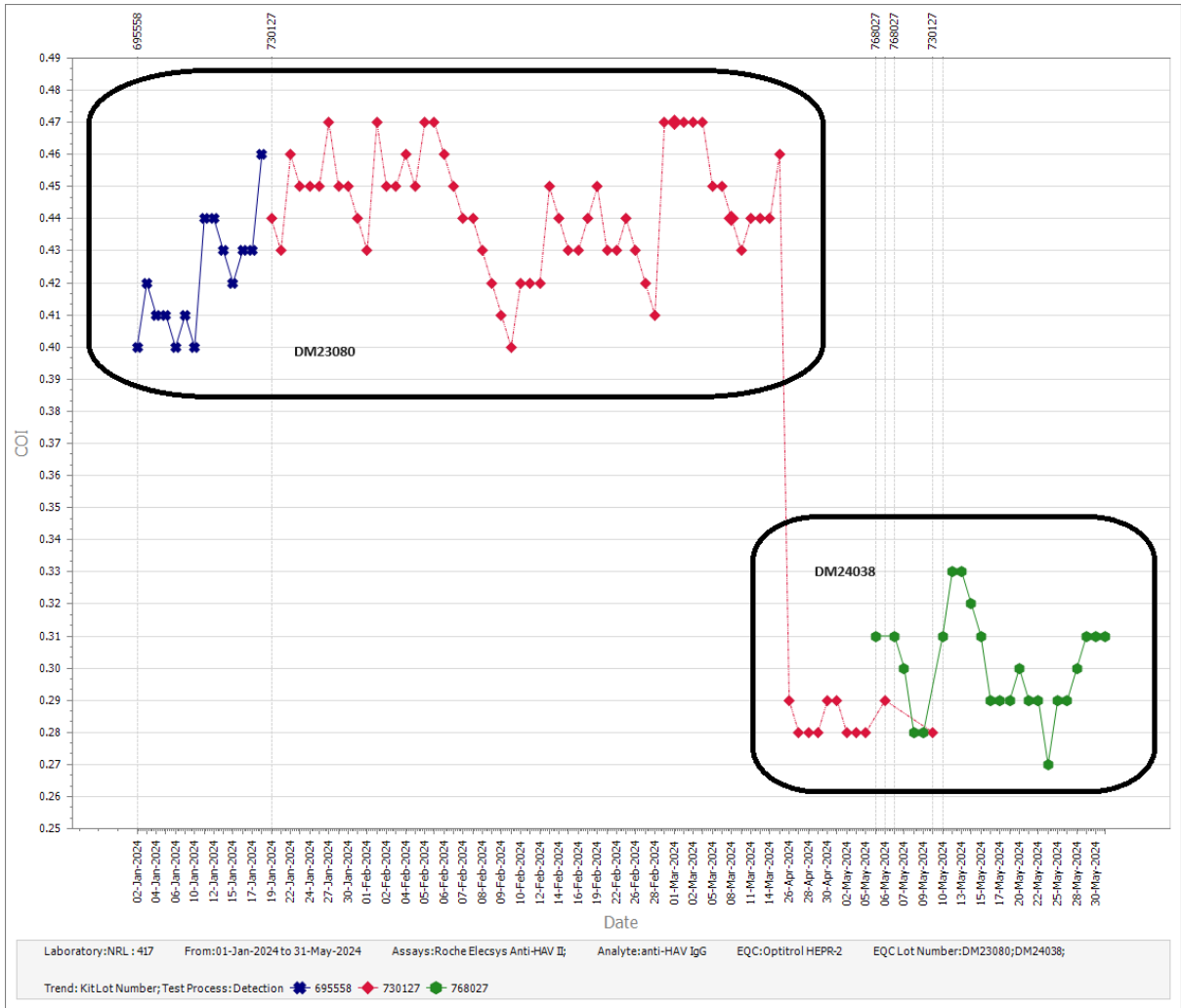


Figure 21 – Participant 417 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Roche Elecsys Anti-HAV II.

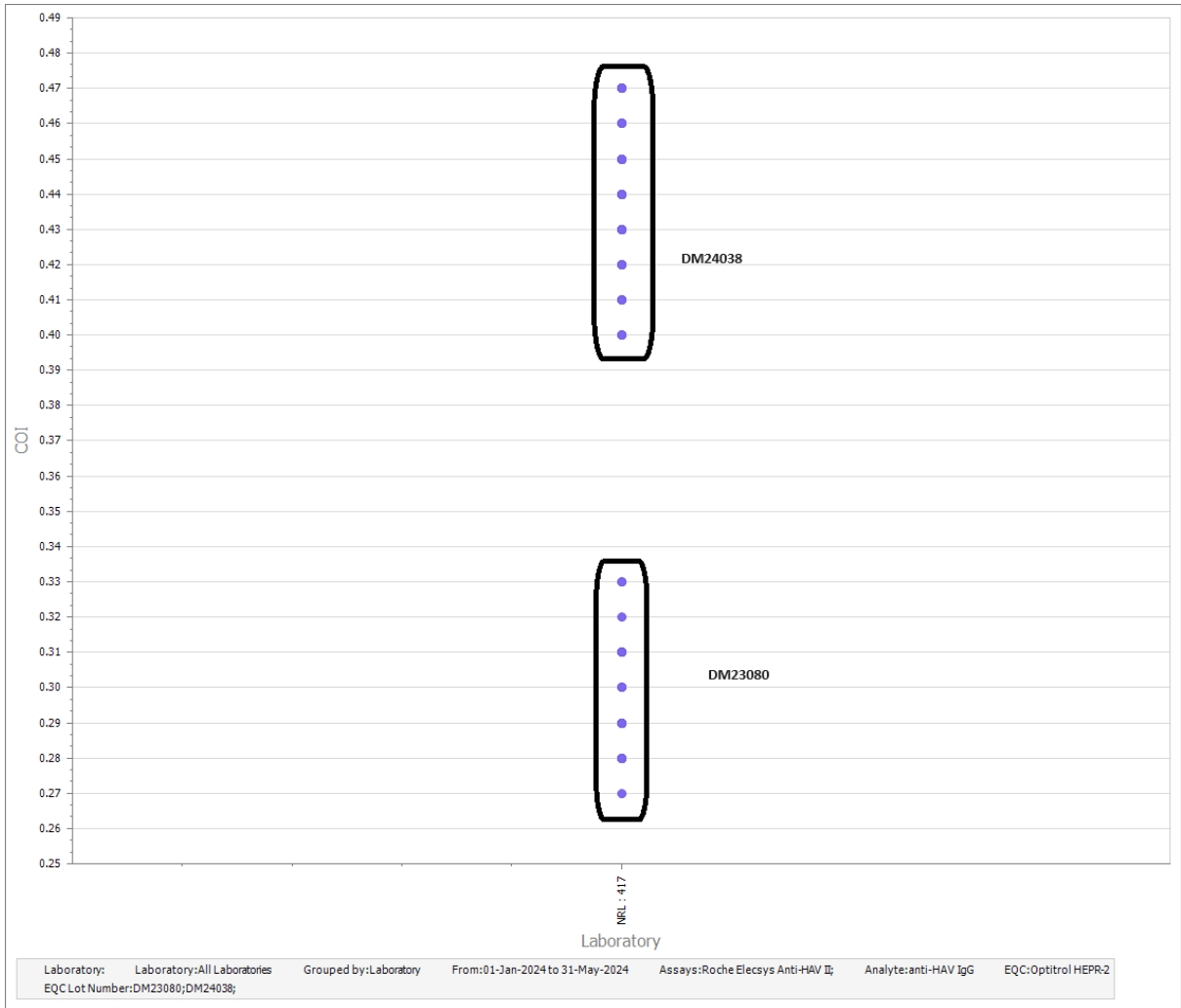


Figure 22 –Peer group data for Optitrol HEPR-2 when tested with Roche Elecsys Anti-HAV II sorted by participant.

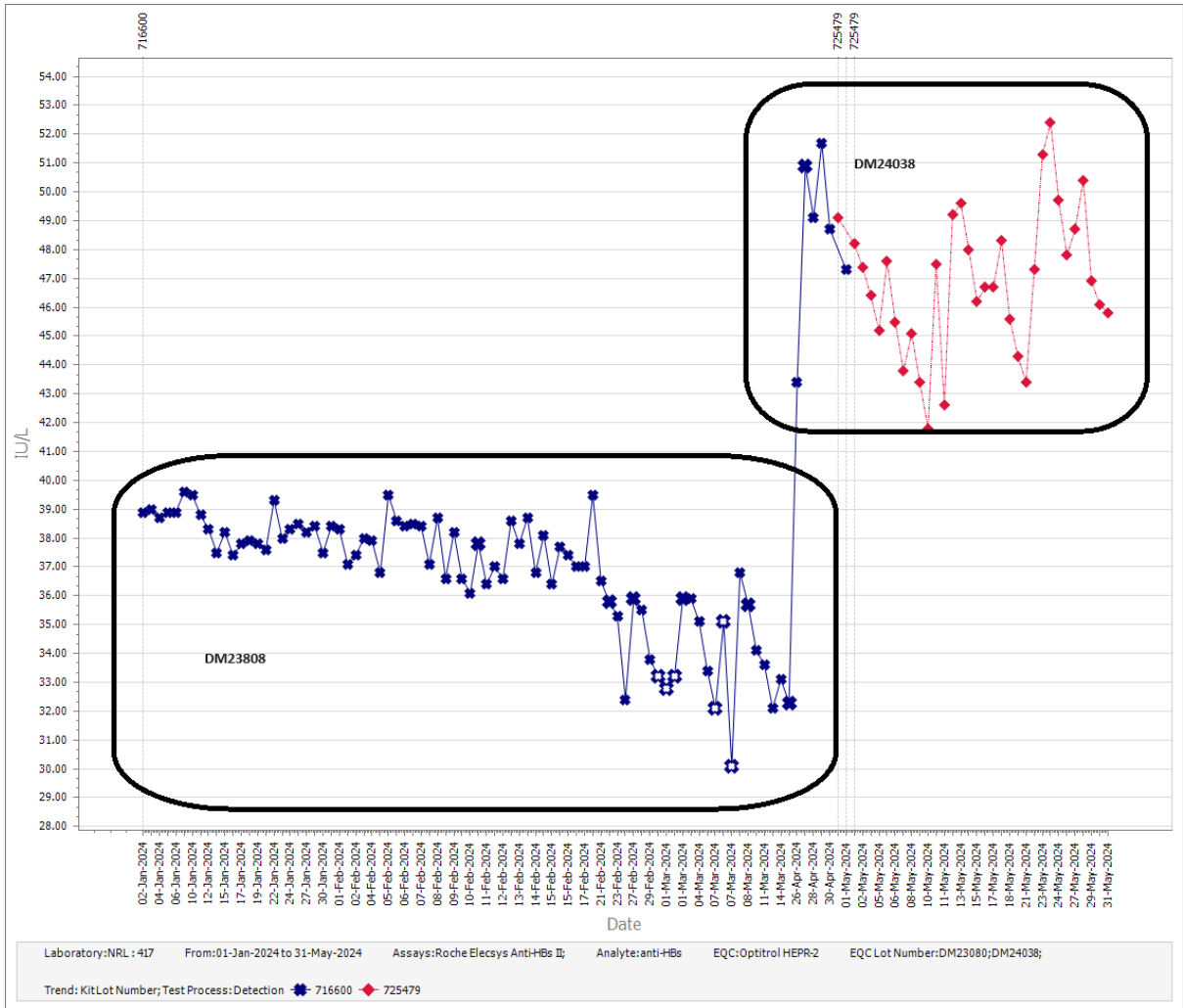


Figure 23 – Participant 417 data demonstrating shift observed for Optitrol HEPR-2 DM24038 when testing with Roche Elecsys Anti-HBs II.

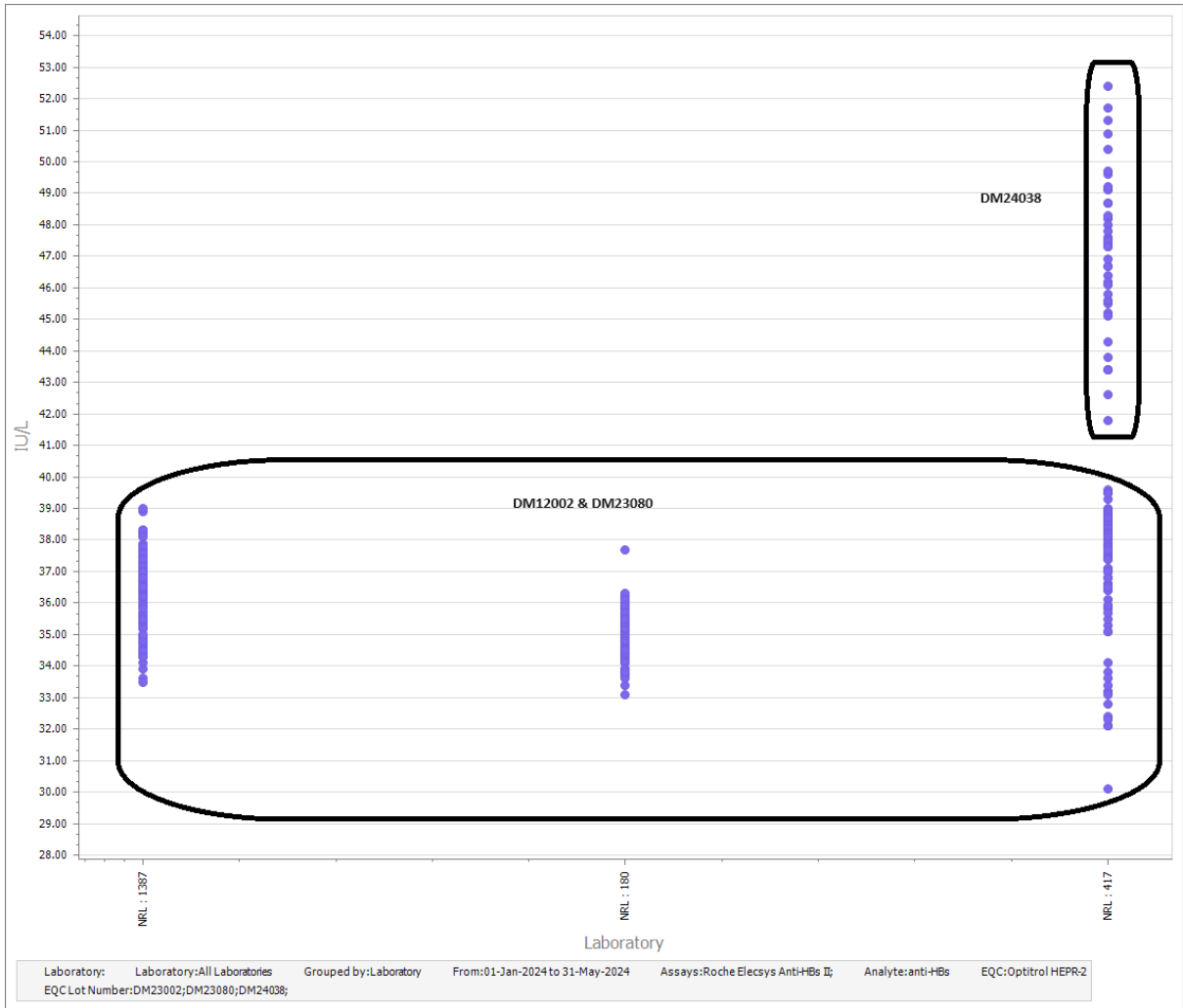


Figure 24 – Peer group data for Optitrol HEPR-2 when tested with Roche Elecsys Anti-HBs II sorted by participant.

Laboratory	n	Mea	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 1015	100	2.53	0.58	1.37	3.69	1.89	5.53	22.85
NRL : 129	174	2.13	0.16	1.81	2.45	1.61	2.57	7.53
NRL : 1321	359	2.65	0.68	1.29	4.01	1.67	5.70	25.61
NRL : 40	59	2.35	0.16	2.02	2.67	2.02	2.88	6.87
NRL : 8	123	2.26	0.22	1.83	2.7	1.86	3.64	9.59
Totals	815	2.44	0.55	1.34	3.55	1.61	5.70	22.6

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott Alinity i HAV Ab - IgG;

Analyte: anti-HAV IgG

EQC: Optitrol HEPR-2

EQC Lot Number: DM23080;

Laboratories: NRL : 8;NRL : 40;NRL : 129;NRL : 1015;NRL : 1321;

Test Kit Lot Numbers: 54256BE00;57170BE00;57173BE00;

Table 1 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i HAV Ab IgG viewed by participant.

Laboratory	n	Mea	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 1015	36	3.82	0.5	2.82	4.81	3.27	5.17	13.02
NRL : 129	17	3.77	0.24	3.3	4.24	3.38	4.34	6.29
NRL : 1321	59	4.22	0.86	2.51	5.93	3.28	6.57	20.28
NRL : 40	19	3.70	0.17	3.36	4.04	3.39	4.00	4.62
NRL : 8	18	4.05	0.19	3.67	4.43	3.73	4.51	4.64
Totals	149	3.98	0.64	2.71	5.25	3.27	6.57	15.94

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott Alinity i HAV Ab - IgG;

Analyte: anti-HAV IgG

EQC: Optitrol HEPR-2

EQC Lot Number: DM24038;

Laboratories: NRL : 8;NRL : 40;NRL : 129;NRL : 1015;NRL : 1321;

Test Kit Lot Numbers: 54256BE00;57170BE00;57173BE00;

Table 2 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott Alinity i HAV Ab IgG viewed by participant.

Laboratory	n	Mea	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 1015	100	23.90	1.73	20.45	27.36	17.55	27.05	7.23
NRL : 129	155	23.99	1.28	21.43	26.55	21.19	31.30	5.34
NRL : 1321	277	22.99	1.49	20.01	25.98	12.68	25.75	6.49
NRL : 40	62	23.10	1.04	21.03	25.18	20.00	25.00	4.48
NRL : 8	132	24.82	1.71	21.41	28.24	19.49	32.47	6.87
Totals	726	23.67	1.64	20.39	26.96	12.68	32.47	6.93

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott Alinity i Anti-HBs;

Analyte: anti-HBs

EQC: Optitrol HEPR-2

EQC Lot Number: DM23080;

Laboratories: NRL : 8;NRL : 40;NRL : 129;NRL : 1015;NRL : 1321;

Test Kit Lot Numbers: 55282FN00;57206FN00;58538FN00;58636FN00;

Table 3 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i Anti-HBs viewed by participant.

Laboratory	n	Mea	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 1015	6	32.04	NA	NA	NA	31.62	32.91	NA
NRL : 129	16	31.81	1.18	29.46	34.16	29.43	33.65	3.69
NRL : 1321	60	31.91	1.78	28.34	35.48	28.90	35.56	5.59
NRL : 40	20	29.60	1.67	26.27	32.93	27.00	33.00	5.63
NRL : 8	16	34.31	3.67	26.98	41.64	29.43	40.90	10.69
Totals	118	31.84	2.38	27.08	36.6	27.00	40.90	7.48

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott Alinity i Anti-HBs;

Analyte: anti-HBs

EQC: Optitrol HEPR-2

EQC Lot Number: DM24038;

Laboratories: NRL : 8;NRL : 40;NRL : 129;NRL : 1015;NRL : 1321;

Test Kit Lot Numbers: 55282FN00;57206FN00;58538FN00;58636FN00;

Table 4 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott Alinity i Anti-HBs viewed by participant.

Laboratory	n	Mea	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 128	30	2.15	0.11	1.93	2.37	1.95	2.35	5.16
NRL : 1869	43	2.34	0.12	2.11	2.57	2.02	2.56	5
NRL : 36	62	2.33	0.23	1.87	2.79	1.87	3.29	9.83
NRL : 43	103	2.18	0.26	1.67	2.7	1.80	3.60	11.81
NRL : 66	21	2.41	0.31	1.79	3.03	2.07	3.57	12.9
NRL : 8	2	2.14	NA	NA	NA	2.05	2.23	NA
Totals	261	2.26	0.24	1.78	2.74	1.80	3.60	10.58

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott ARCHITECT HAVAb - IgG;

Analyte: anti-HAV IgG

EQC: Optitrol HEPR-2

EQC Lot Number: DM23080;

Test Kit Lot Numbers: 54254BE00;54255BE00;57182BE00;

Table 5 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott Alinity i Anti-HBs viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 128	10	3.99	0.41	3.16	4.82	3.51	4.63	10.37
NRL : 36	19	3.72	0.3	3.12	4.33	3.12	4.33	8.14
NRL : 43	84	3.49	0.21	3.06	3.91	3.09	4.02	6.08
Totals	113	3.57	0.3	2.98	4.16	3.09	4.63	8.26

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Laboratory

From: 01-Jan-2024 to 01-Jul-2024

Assays: Abbott ARCHITECT HAVAb - IgG;

Analyte: anti-HAV IgG

EQC: Optitrol HEPR-2

EQC Lot Number: DM24038;

Test Kit Lot Numbers: 54254BE00;54255BE00;57182BE00;

Table 6 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott ARCHITECT HAVAb IgG viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 128	40	24.28	0.69	22.89	25.67	22.65	25.51	2.86
NRL : 36	59	23.82	1.29	21.25	26.39	21.22	26.22	5.4
NRL : 43	96	24.73	3.07	18.6	30.86	21.77	37.74	12.4
Totals	195	24.36	2.31	19.73	28.99	21.22	37.74	9.5

Legend:

Laboratory:
Laboratory: All Laboratories
Grouped by: Laboratory
From: 01-Jan-2024 to 01-Jul-2024
Assays: Abbott ARCHITECT Anti-HBs;
EQC: Optitrol HEPR-2
EQC Lot Number: DM23080;
Laboratories: NRL : 36;NRL : 43;NRL : 128;
Test Kit Lot Numbers: 55360FN00;57150FN00;59318FZ00;60249FZ00;

Table 7 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Abbott ARCHITECT Anti-HBs viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 128	9	31.95	NA	NA	NA	31.27	32.91	NA
NRL : 36	7	30.12	NA	NA	NA	28.90	31.83	NA
NRL : 43	82	32.54	1.82	28.91	36.18	29.14	37.82	5.58
Totals	98	32.31	1.8	28.71	35.92	28.90	37.82	5.58

Legend:

Laboratory:
Laboratory: All Laboratories
Grouped by: Laboratory
From: 01-Jan-2024 to 01-Jul-2024
Assays: Abbott ARCHITECT Anti-HBs;
EQC: Optitrol HEPR-2
EQC Lot Number: DM24038;
Laboratories: NRL : 36;NRL : 43;NRL : 128;
Test Kit Lot Numbers: 55360FN00;57150FN00;59318FZ00;60249FZ00;

Table 8 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Abbott ARCHITECT Anti-HBs viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 417	84	0.40	0.06	0.27	0.53	0.29	0.47	16.08
Totals	84	0.40	0.06	0.27	0.53	0.29	0.47	16.08

Legend:

Laboratory:
 Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2024 to 01-Jul-2024
 Assays: Roche Elecsys Anti-HAV II;
 Analyte: anti-HAV IgG
 EQC: Optitrol HEPR-2
 EQC Lot Number: DM23080;
 Test Kit Lot Numbers: 730127;768027;

Table 9 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Roche Elecsys Anti-HAV II viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 417	29	0.29	0.02	0.26	0.33	0.27	0.33	5.46
Totals	29	0.29	0.02	0.26	0.33	0.27	0.33	5.46

Legend:

Laboratory:
 Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2024 to 01-Jul-2024
 Assays: Roche Elecsys Anti-HAV II;
 Analyte: anti-HAV IgG
 EQC: Optitrol HEPR-2
 EQC Lot Number: DM24038;
 Test Kit Lot Numbers: 730127;768027;

Table 10 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Roche Elecsys Anti-HAV II viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 417	74	37.16	1.8	33.57	40.75	32.10	39.60	4.83
Totals	74	37.16	1.8	33.57	40.75	32.10	39.60	4.83

Legend:

Laboratory:
 Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2024 to 01-Jul-2024
 Assays: Roche Elecsys Anti-HBs
 Analyte: anti-HBs
 EQC: Optitrol HEPR-2
 EQC Lot Number: DM23080;
 Laboratories: NRL : 417;
 Test Kit Lot Numbers: 716600;

Table 11 –Mean peer group data for Optitrol HEPR-2 DM23080 when tested with Roche Elecsys Anti-HBs II viewed by participant.

Laboratory	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
NRL : 417	9	49.33	NA	NA	NA	43.40	51.70	NA
Totals	9	49.33	NA	NA	NA	43.40	51.70	NA

Legend:

Laboratory:
 Laboratory: All Laboratories
 Grouped by: Laboratory
 From: 01-Jan-2024 to 01-Jul-2024
 Assays: Roche Elecsys Anti-HBs
 Analyte: anti-HBs
 EQC: Optitrol HEPR-2
 EQC Lot Number: DM24038;
 Laboratories: NRL : 417;
 Test Kit Lot Numbers: 716600;

Table 12 –Mean peer group data for Optitrol HEPR-2 DM24038 when tested with Roche Elecsys Anti-HBs II viewed by participant.