



QC Services Investigation:

PMM-QC-1480

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Released: August 2023

INTRODUCTION

Participant 826 contacted NRL regarding a shift down in data observed for Optitrol Blue lot DM22009 when testing with the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay for reagent lots 45574FN00 and 47571FN00. NRL investigated all data reported by the peer group and those participants testing with reagent lots 45574FN00 and 47571FN00 in combination with other Optitrol Blue QC lots, other Alinity i HBsAg Next lots and other Abbott platforms (Alinity s and ARCHITECT).

FINDINGS

This investigation looked at all peer group data for the same assay reagent and Optitrol Blue lot and any other Optitrol Blue lot with data reported to EDCNet using the reagent lots in question (45574FN00 and 47571FN00), to establish whether these reagent lots were the source of any variation observed. Below are the full listing of charts and tables included in the investigation:

- Figure 1 – Participant 826 Levy Jennings chart grouped by reagent lot illustrating a shift down in data for Optitrol Blue DM22009 when testing on the Abbott Alinity I HBsAg Next Qualitative Reagent Kit assay for reagent lots 45574FN00 and 47571FN00.
- Figure 2 – Participant 826 Levy Jennings chart illustrating shift down in data on reagent lots 45574FN00 and 47571FN00 testing with Optitrol Blue DM22009 on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by operator.
- Figure 3 – Peer group data for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay sorted by participants.
- Figure 4 – Peer group data for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay sorted by reagent lot.
- Figure 5 – Peer group data and mean S/Co values for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay sorted by reagent lot.
- Figure 6 – Participant 83 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lots 45574FN00 and 47571FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with by reagent lot.
- Figure 7 – Participant 809 Levy Jennings chart testing with Optitrol Blue DM22009 on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 8. Participant 809 mean/scatter chart testing with Optitrol Blue DM22009 on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot and mean values.
- Figure 9 – Participant 810 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lots 45574FN00 and 47571FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 10 – Participant 811 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lot 45574FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 11 – Participant 816 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lot 45574FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.

- Figure 12 – Participant 817 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lot 45574FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 13 – Participant 818 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lots 45574FN00 and 47571FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 14 – Participant 825 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM22009 on reagent lots 45574FN00 and 47571FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 15 – Participant 30 Levy Jennings chart illustrating shift down in data for Optitrol Blue DM21187 and DM22009 on reagent lots 45561FN00 and 47508FN00 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Figure 16 – Peer group data for Optitrol Blue lots DM21057, DM21187, DM22009 and DM22121 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay sorted by reagent lot.
- Table 1 – Peer group data for Optitrol Blue DM22009 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.
- Table 2. Peer group data for Optitrol Blue lots DM21057, DM21187, DM22009 and DM22121 testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.

DISCUSSION

Figures 1 through 5 each show data for both Participant 826 and the peer group that demonstrates HBsAg marker performance for Optitrol Blue lot DM22009, when tested with the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay, with consistent data reported for reagent lots prior to lot 45574FN00 and 47571FN00. Data reported for these reagent lots show a shift down in S/Co values. All reported data falls inside the QConnect Limits of S/Co 13.10 – 21.70. Further investigation demonstrated that this shift down was observed for reagent lots 45561FN00 and 47508FN00 for Participant 30 testing with Optitrol Blue DM21187 and DM22009 (Figures 14 and 15). These reagent lots are not in use by any other participant within the peer group, likely due to differing geographical locations.

Figures 6 through 14 each show data for each individual participant within the peer group demonstrating the same shift down observed for Participant 826 for reagent lots 45574FN00 and 47571FN00, testing with Optitrol Blue DM22009. Not all participants in the peer group reported data for both reagent lots, but at least one of the reagent lots was in use at each participant site. Participant 809 (figure 7) is the only participant in the peer group where the shift down was not observed for reagent lot 45574FN00; however, this is likely due to the laboratory data also running below the peer group for the previous reagent lot in use (43342FN00). Data from Participant 809 for reagent lot 45574FN00 were consistent with peer group data (figure 8).

Figure 16 shows peer group data for Optitrol Blue lots DM21057, DM21187, DM22009 and DM22121 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay. Data reported for these Optitrol Blue lots show a shift down in data when testing with previously identified reagent lots 45561FN00, 45574FN00, 47508FN00 and 47571FN00.

Tables 1 and 2 show peer group data for data reported to EDCNet from Jan 1st, 2022, to 26th July 2023 for the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay testing with Optitrol Blue lot DM22009 (table 1) and all Optitrol Blue lots in use, DM21057, DM21187, DM22009 and DM22121 (table 2). Both tables illustrate a decrease in mean S/Co value for data entered under reagent lots 45561FN00, 45574FN00, 47508FN00 and 47571FN00 in comparison to previous reagent lots in use.

Table 1 shows a mean S/Co of 15.28, 15.09 and 15.09 for reagent lots 45574FN00, 47508FN00 and 47571FN00, respectively in comparison to the mean of all other reagent lots in use (reported as a S/Co of 17.24).

Table 2 shows a mean S/Co of 14.91, 15.30, 15.06 and 15.12 for reagent lots 45561FN00, 45574FN00, 47508FN00 and 47571FN00, respectively in comparison to the mean of all other reagent lots in use (reported as a S/Co of 16.70).

CONCLUSIONS

The shift down in S/Co observed by Participant 826 for reagent lots 45574FN00 and 47571FN00 on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay is a result of reagent lot variation. This was also observed for reagent lots 45561FN00 and 47508FN00 across the peer group and likely to be observed in subsequent batches.

RECOMMENDATIONS

NRL recommends participants monitor these lots with the peer group data.

NRL recommends participants monitor data using QConnect Limits provided in EDCNet.

NRL recommends participants review Abbott Certificate of Analysis certificates (CoAs) for reagent lots received as these can indicate a potential shift.

For more information or request assistance with calculating and setting Laboratory Limits please contact NRL on [**qconnect@nrlquality.org.au**](mailto:qconnect@nrlquality.org.au)

NRL will continue to monitor Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay.

APPENDIX

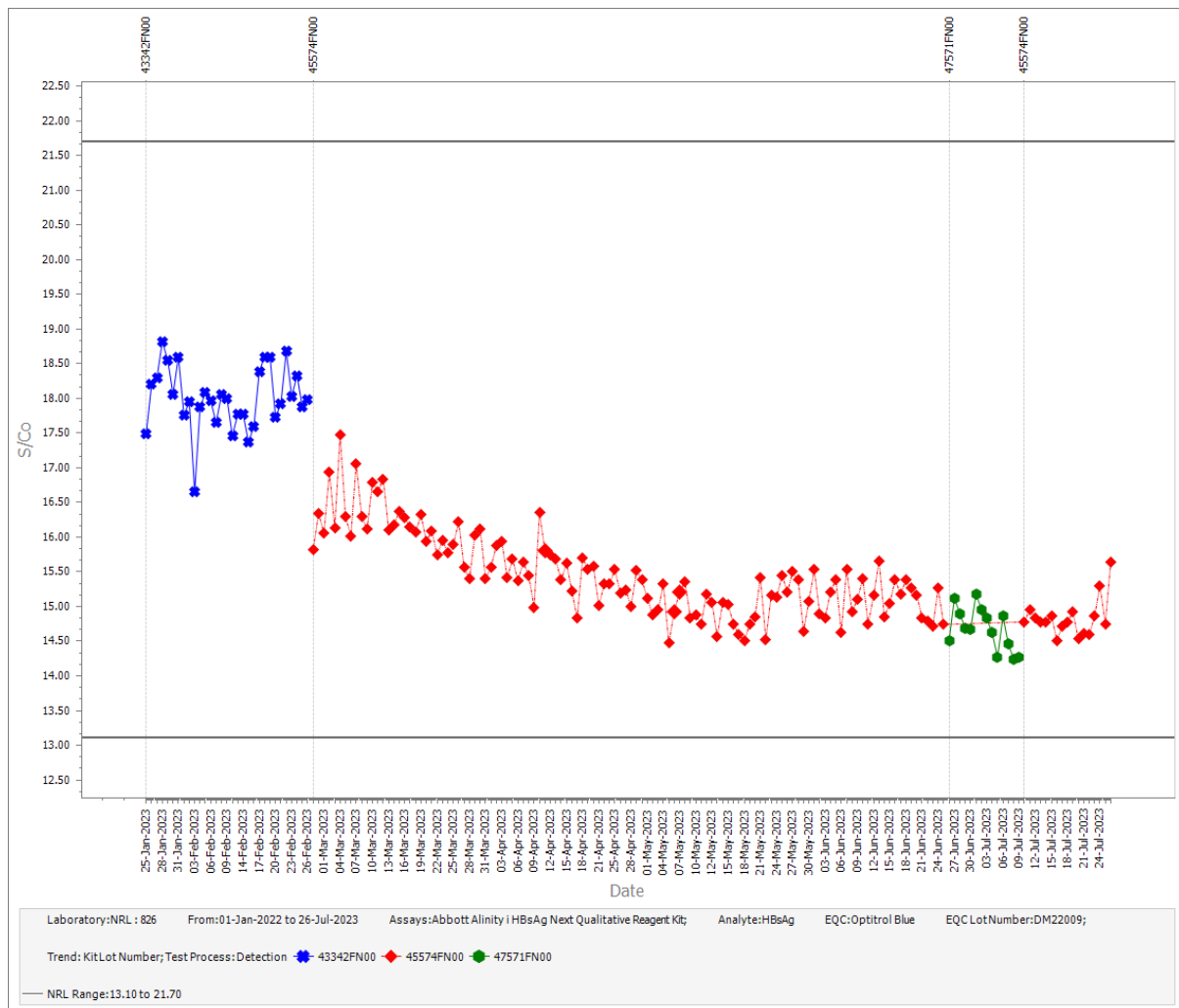


Figure 1. Participant 826 Abbott Alinity i HBsAg Next Qualitative Reagent Kit / Optitrol Blue DM22009 data by reagent lot.

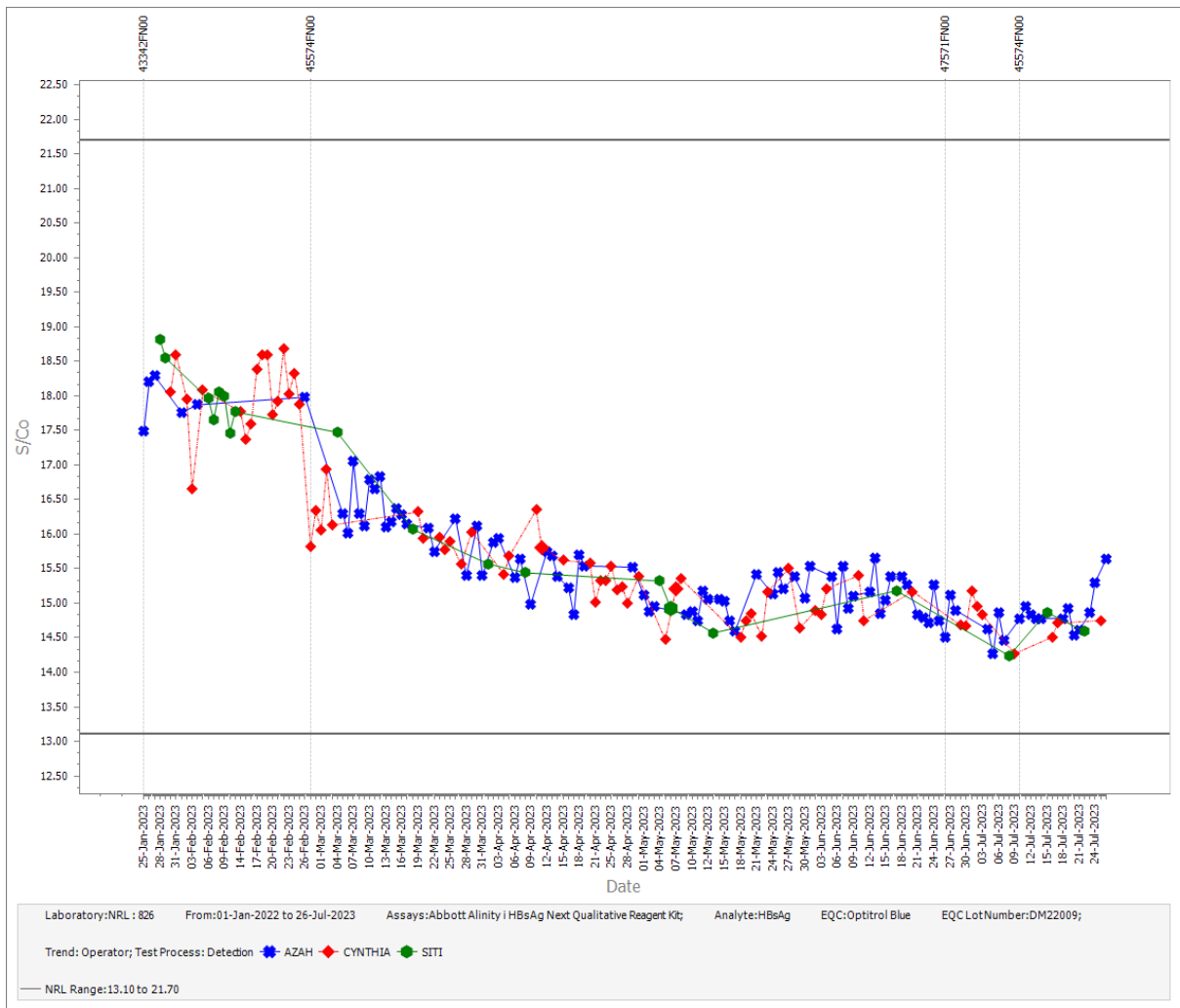


Figure 2. Participant 826 Abbott Alinity i HBsAg Next Qualitative Reagent Kit / Optitrol Blue DM22009 data by operator.

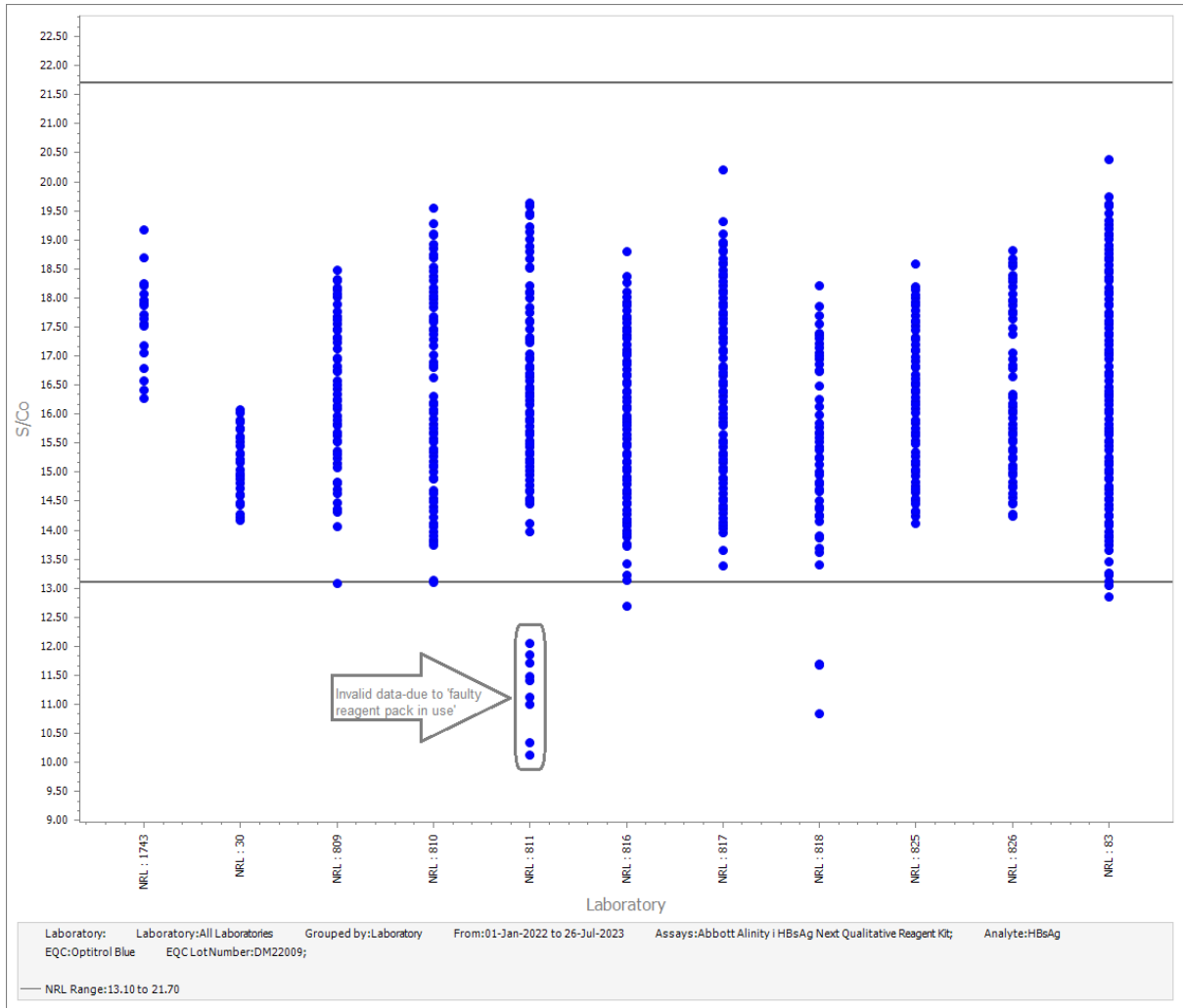


Figure 3. Peer group data for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by participants.

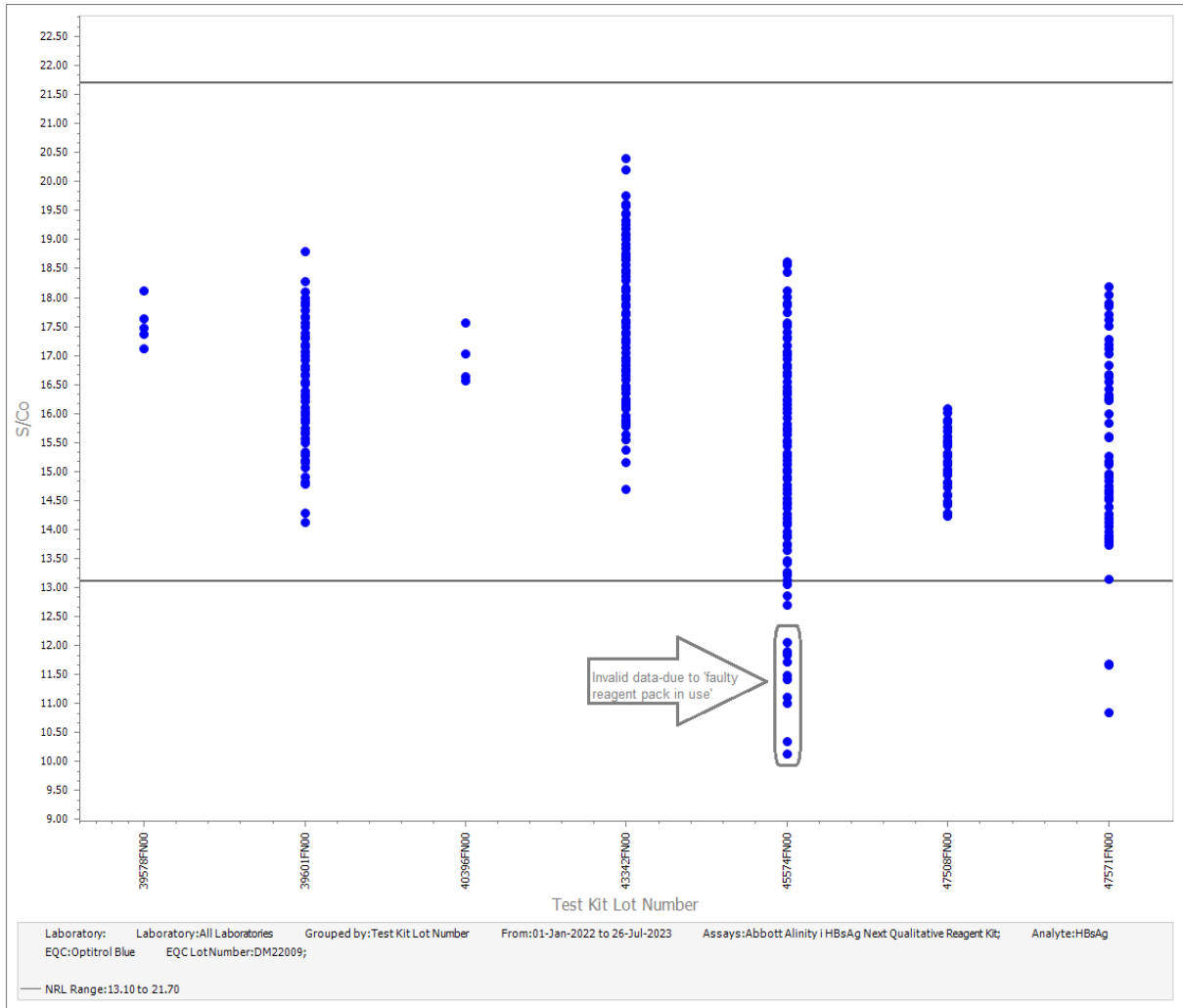


Figure 4. Peer group data for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.

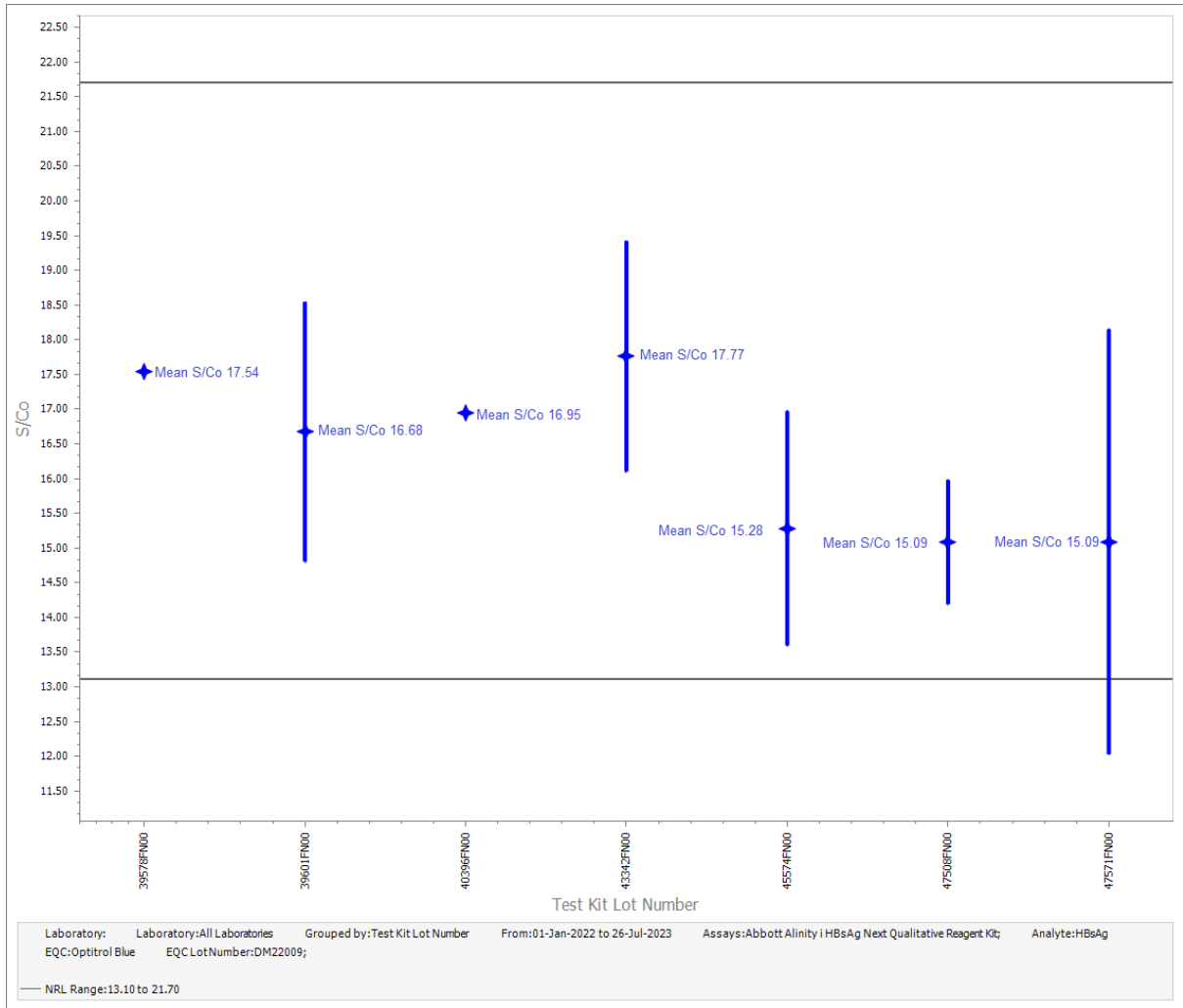


Figure 5. Peer group data and mean S/Co values for Optitrol Blue lot DM22009 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot.

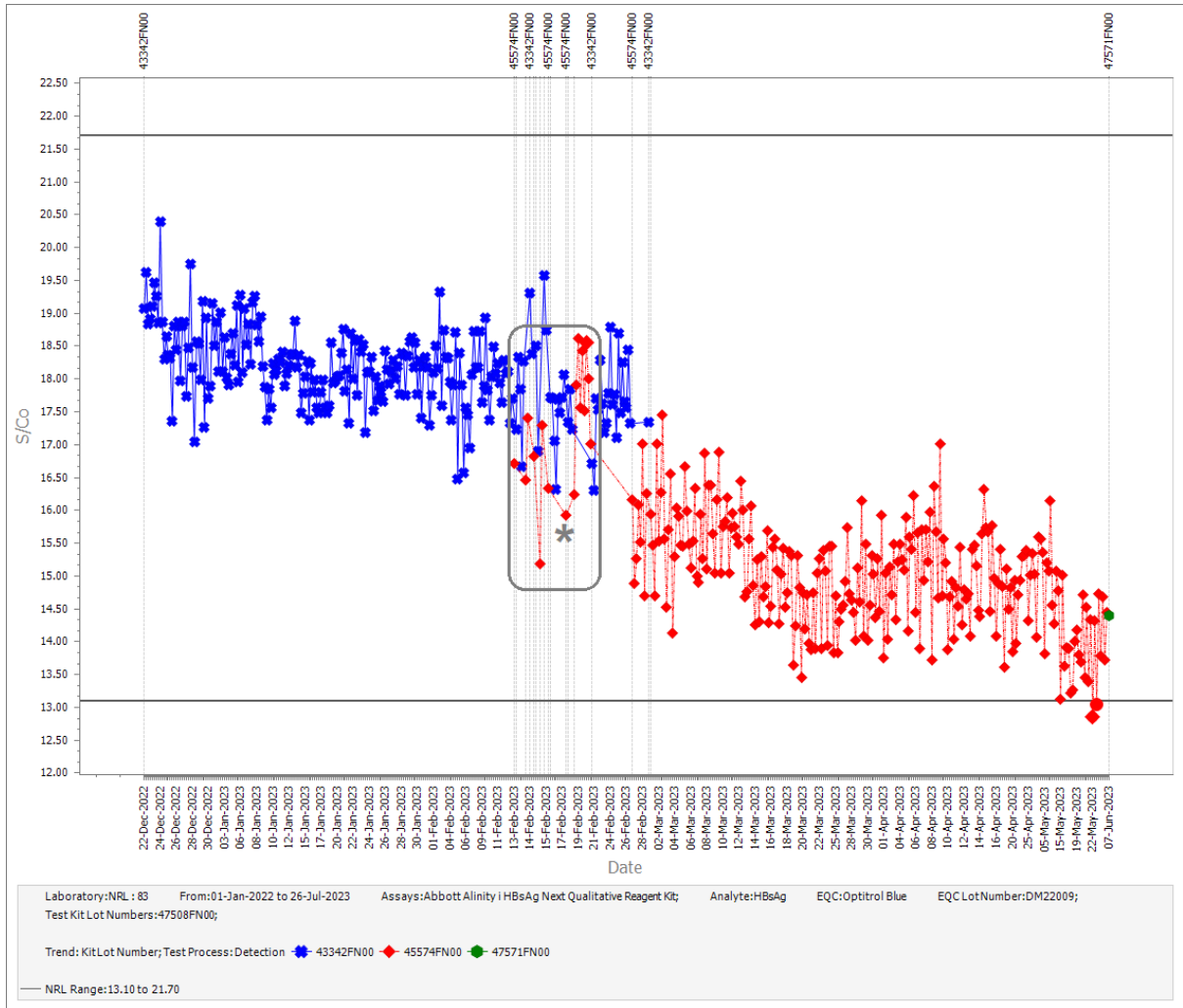


Figure 6. Participant 83 data on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

* Data entry under review by lab – PMM-QC-1478.

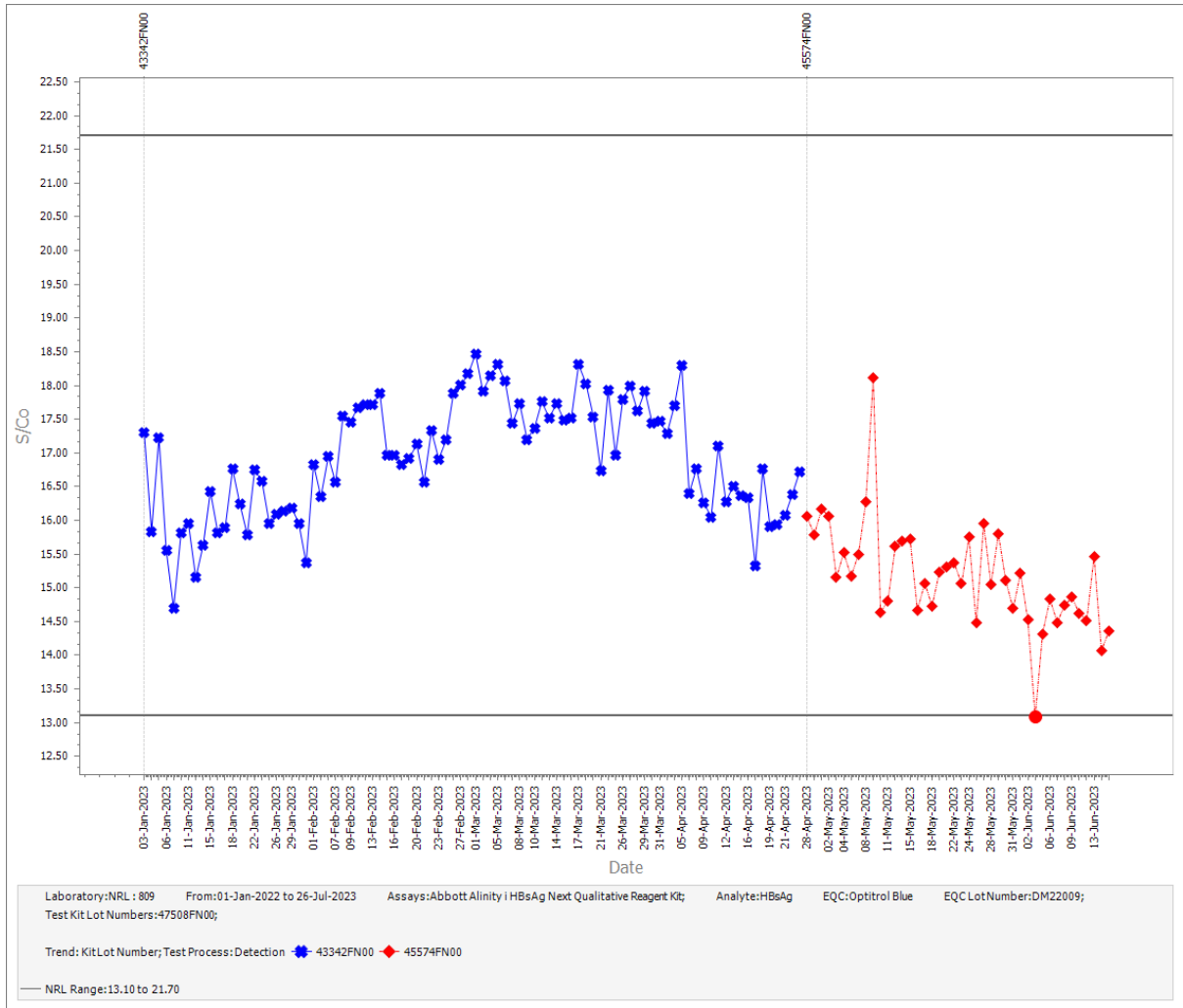


Figure 7. Participant 809 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

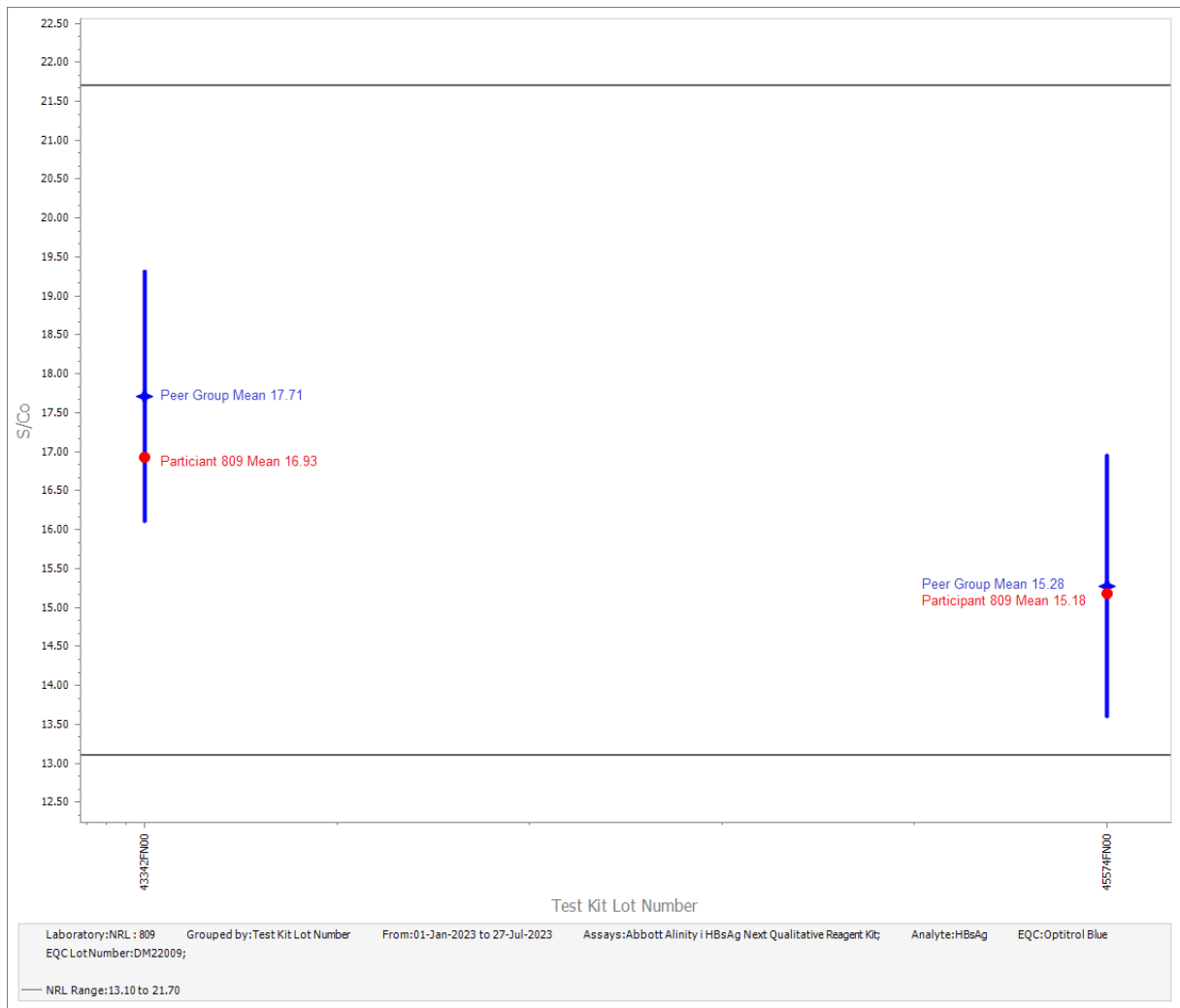


Figure 8. Participant 809 mean/scatter chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot and mean values.

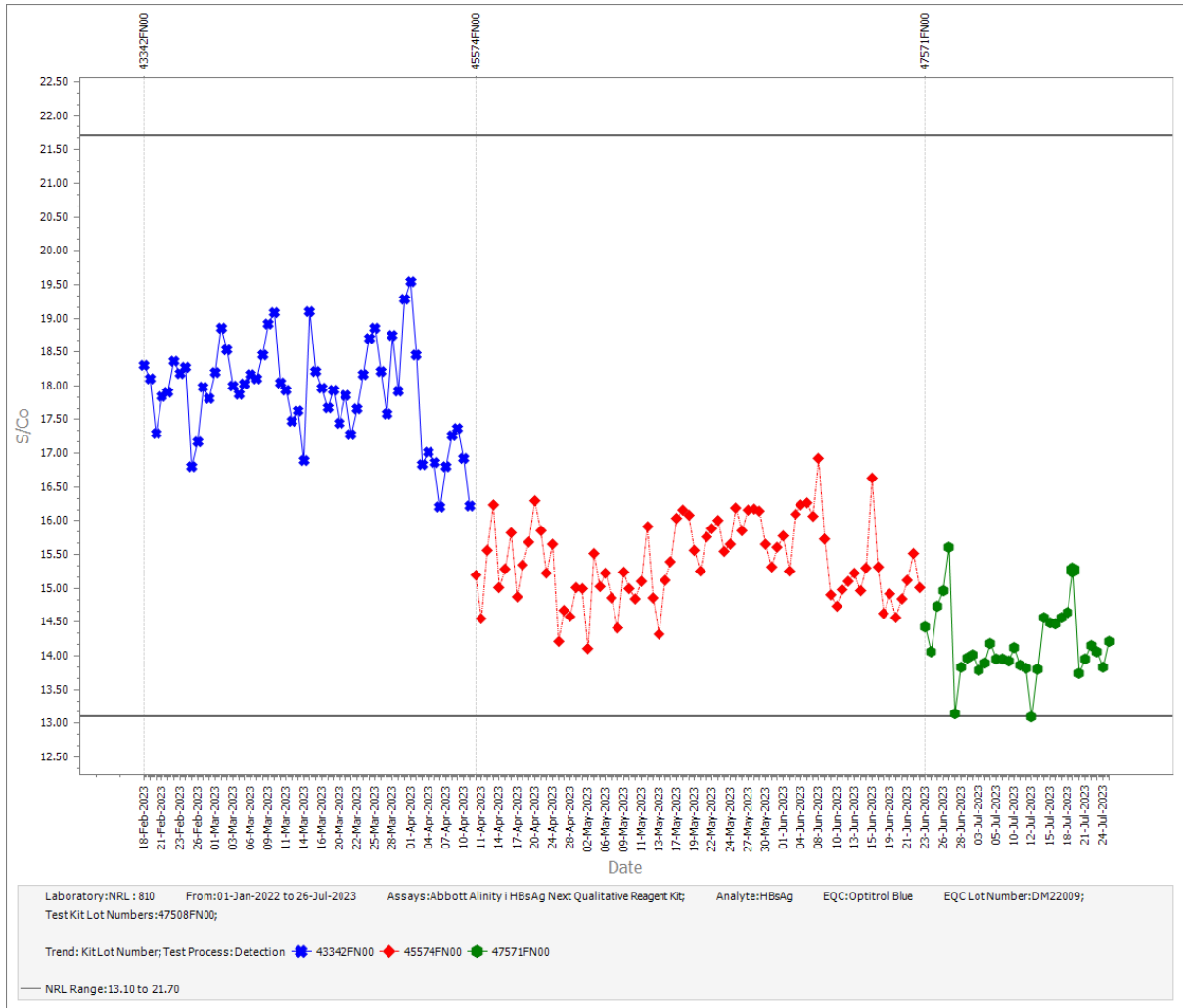


Figure 9. Participant 810 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

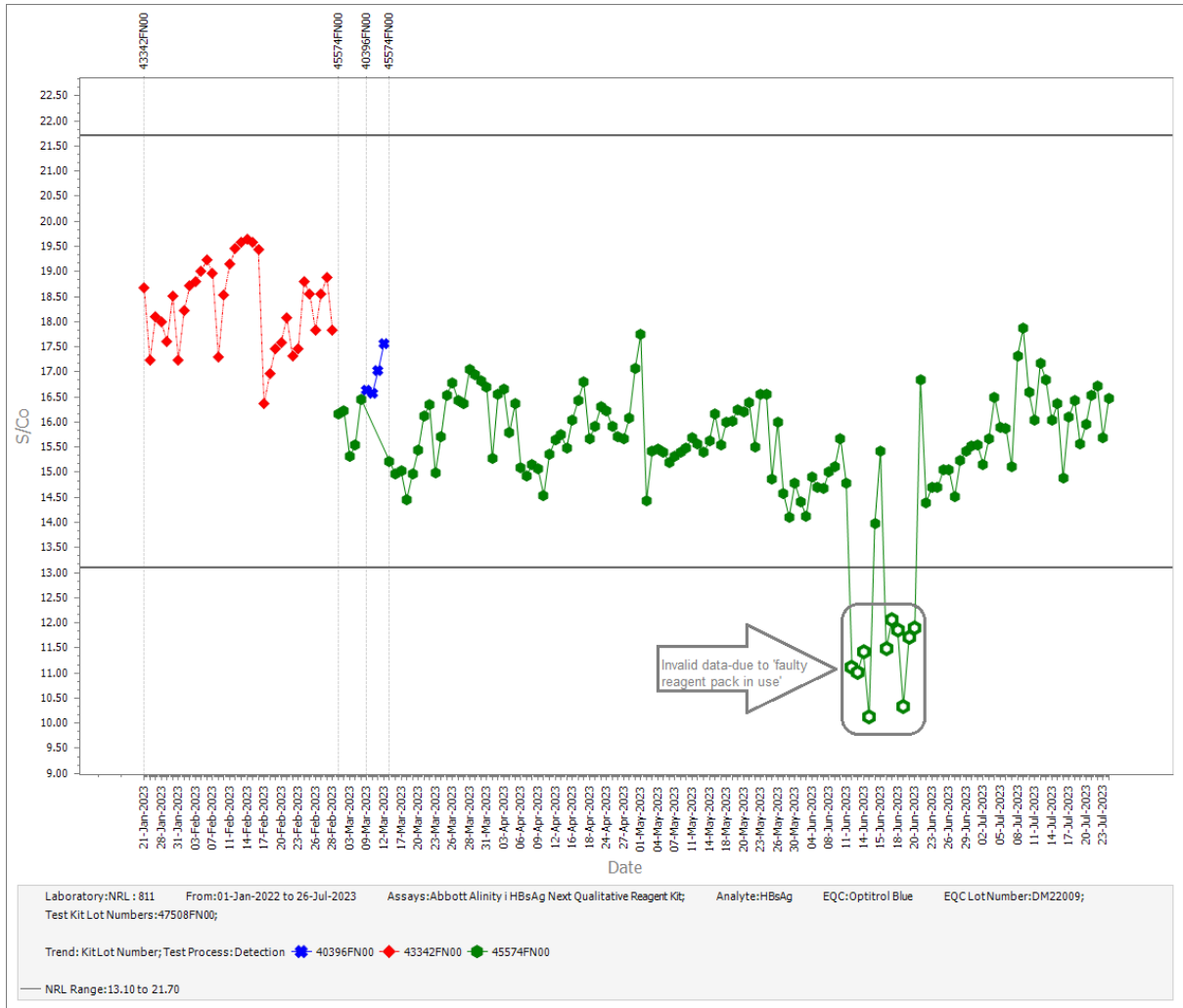


Figure 10. Participant 811 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

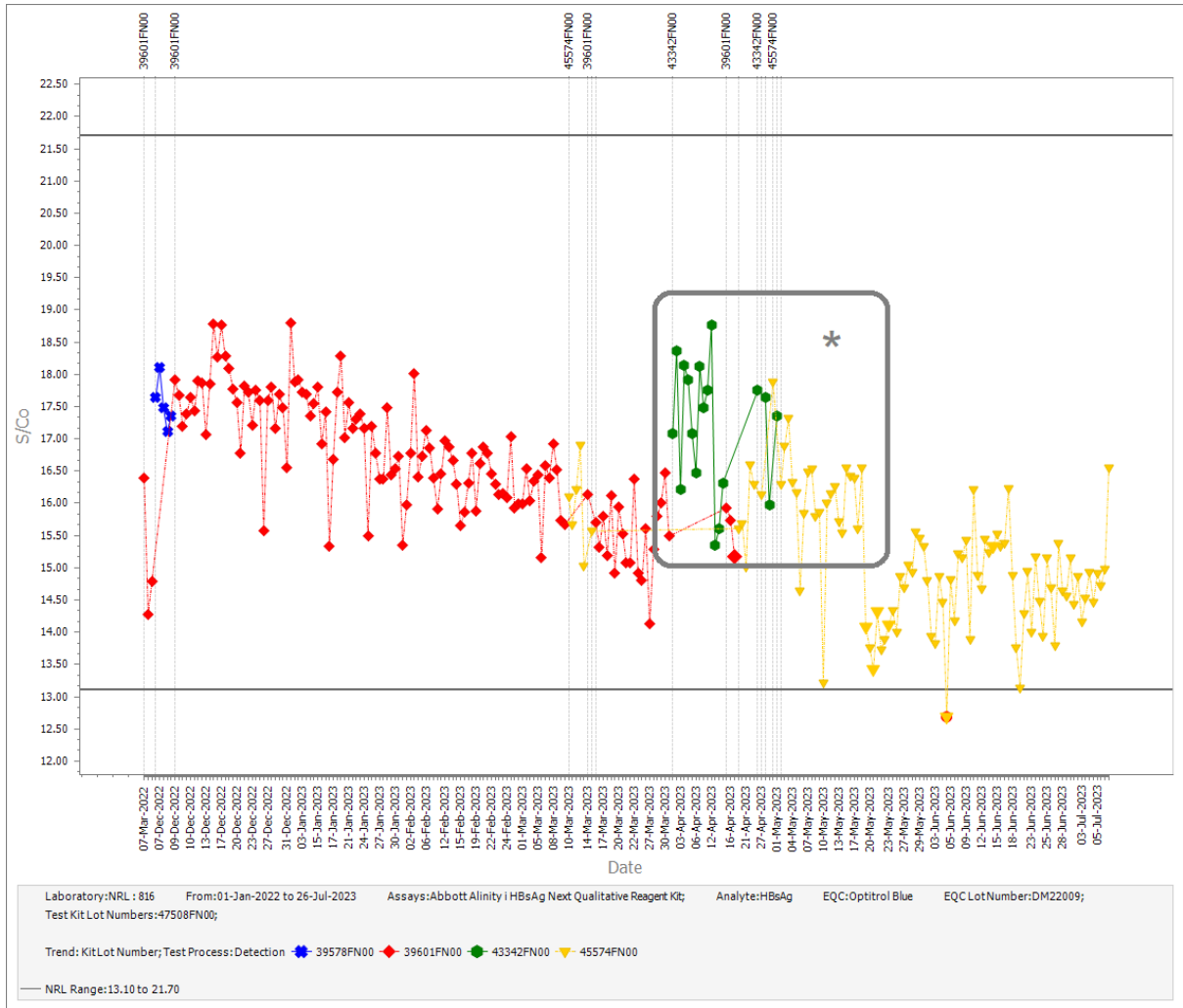


Figure 11. Participant 816 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

* Reagent lot data entry under review by lab – PMM-QC-1481.

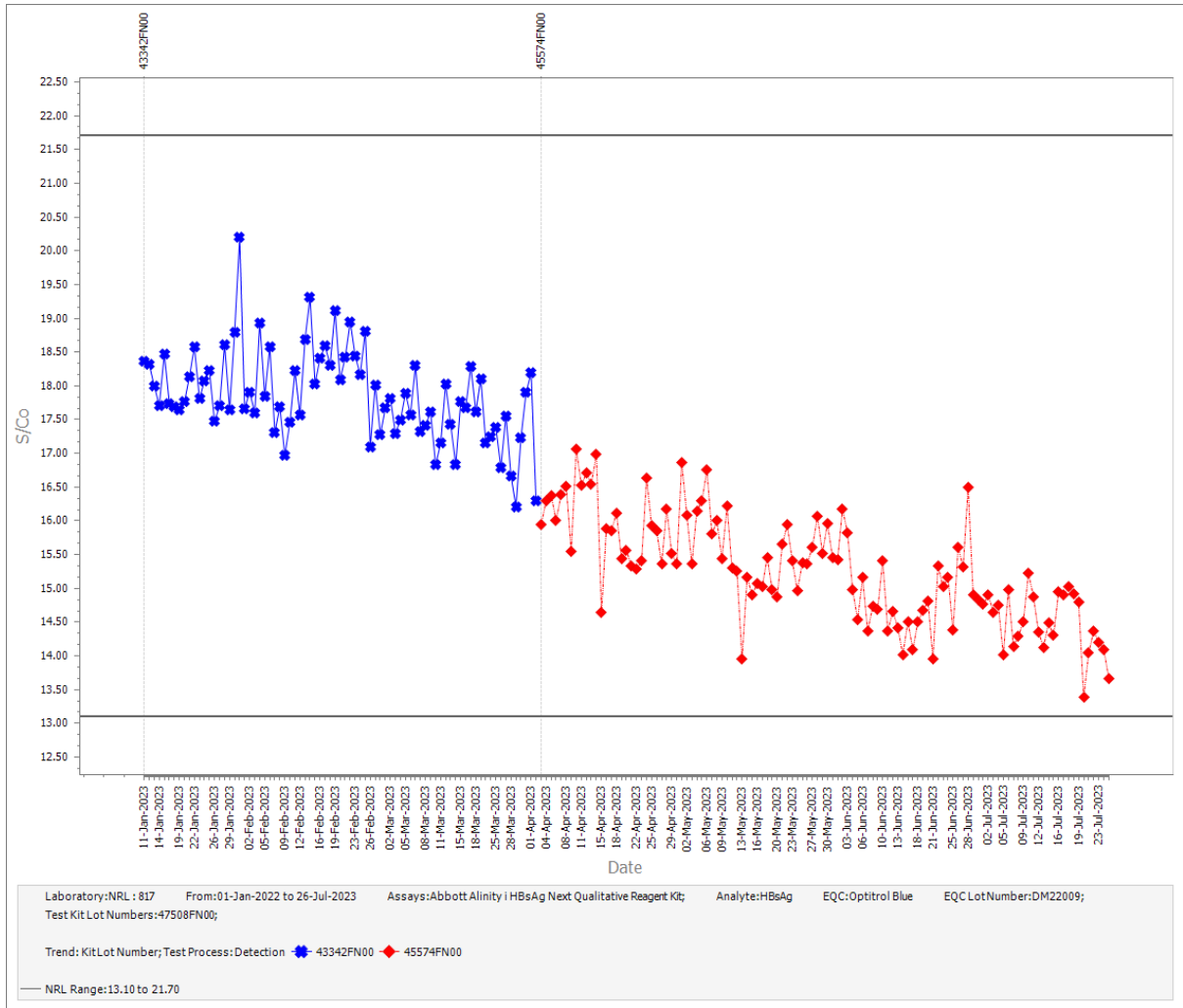


Figure 12. Participant 817 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

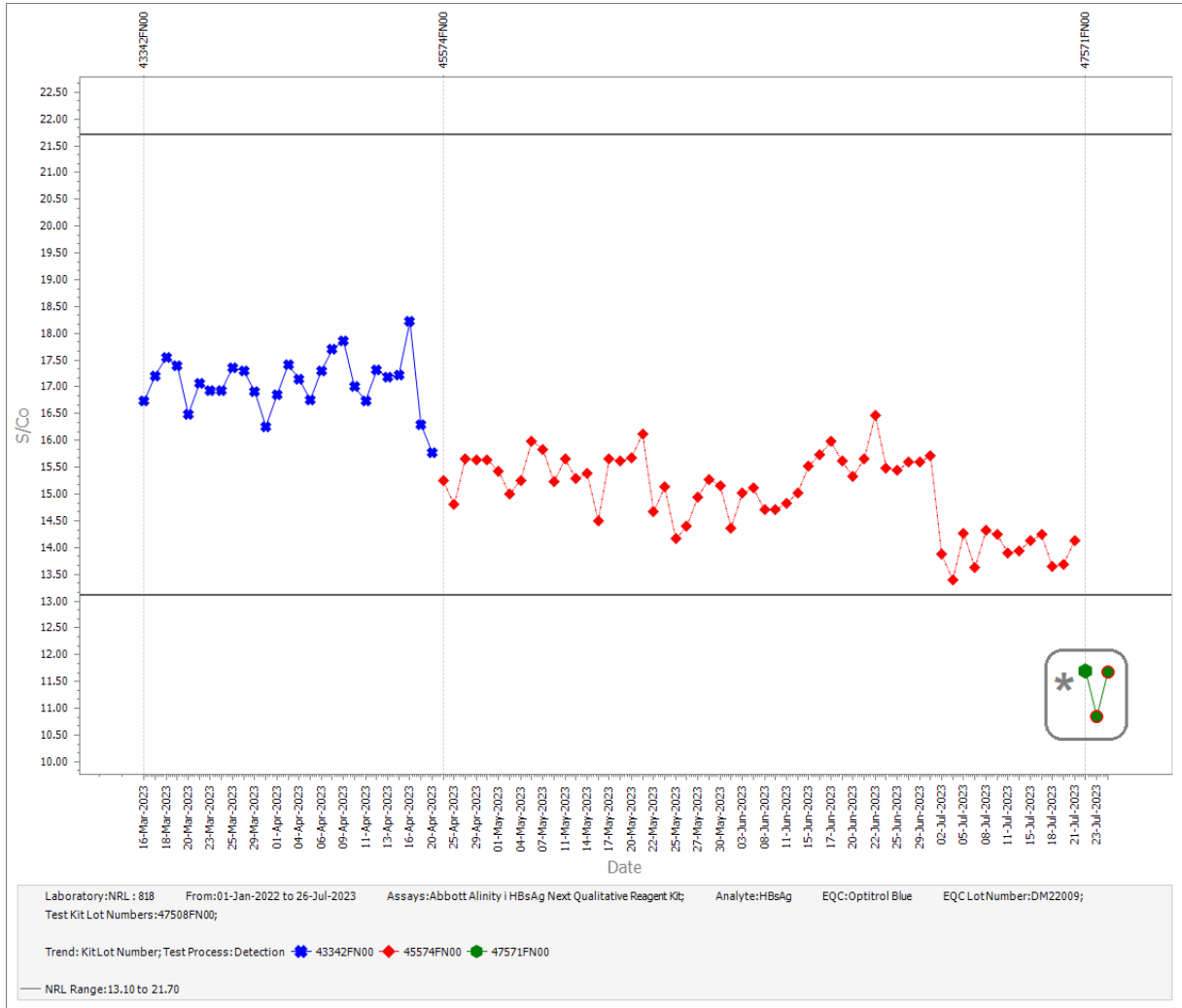


Figure 13. Participant 818 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

* Reagent lot calibration and pack usage under review by lab – PMM-QC-1477.

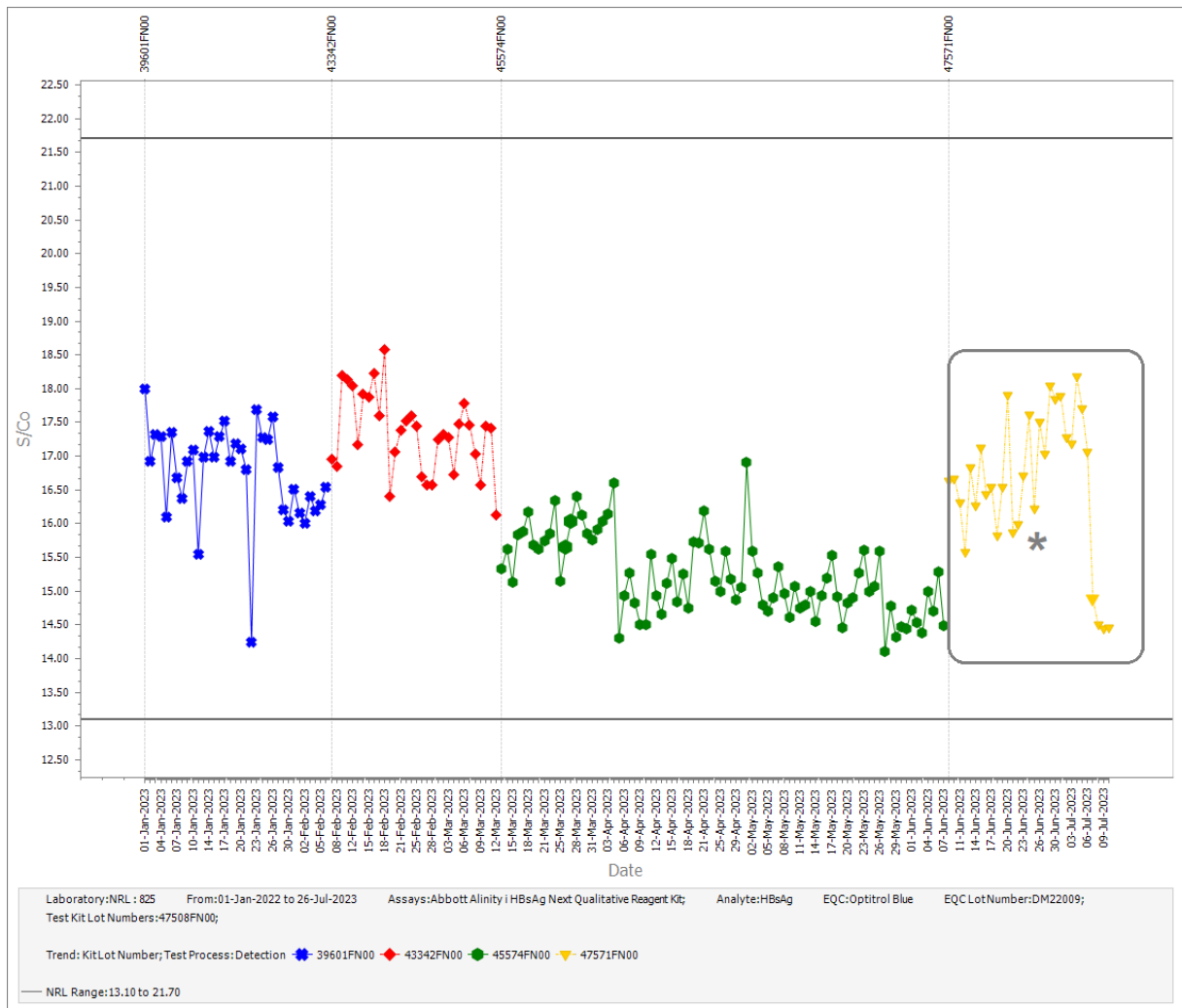


Figure 14. Participant 818 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

* Data entry under review by lab – PMM-QC-1476.

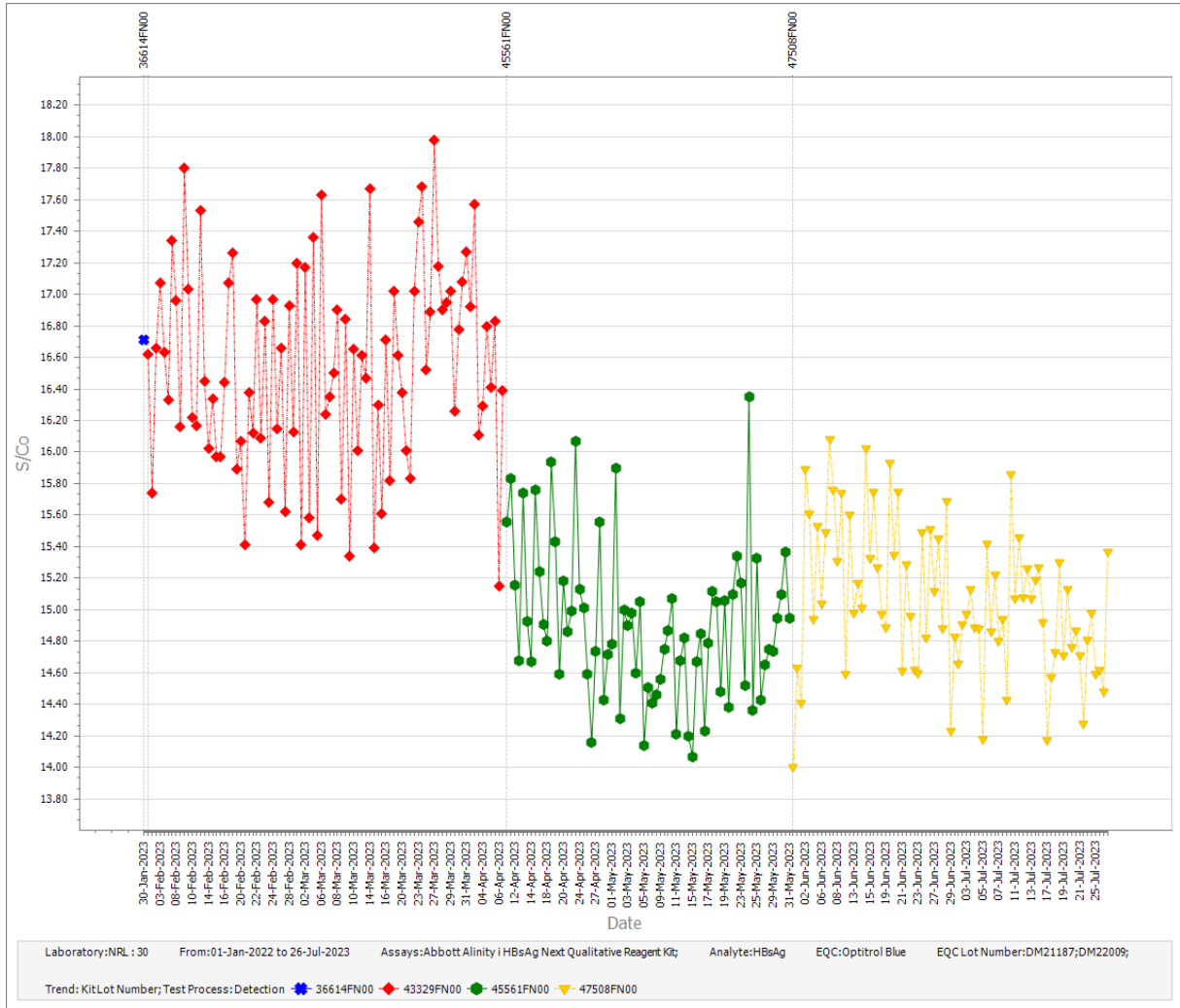


Figure 15. Participant 30 Levy Jennings chart testing on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM21187 and DM22009 by reagent lot.

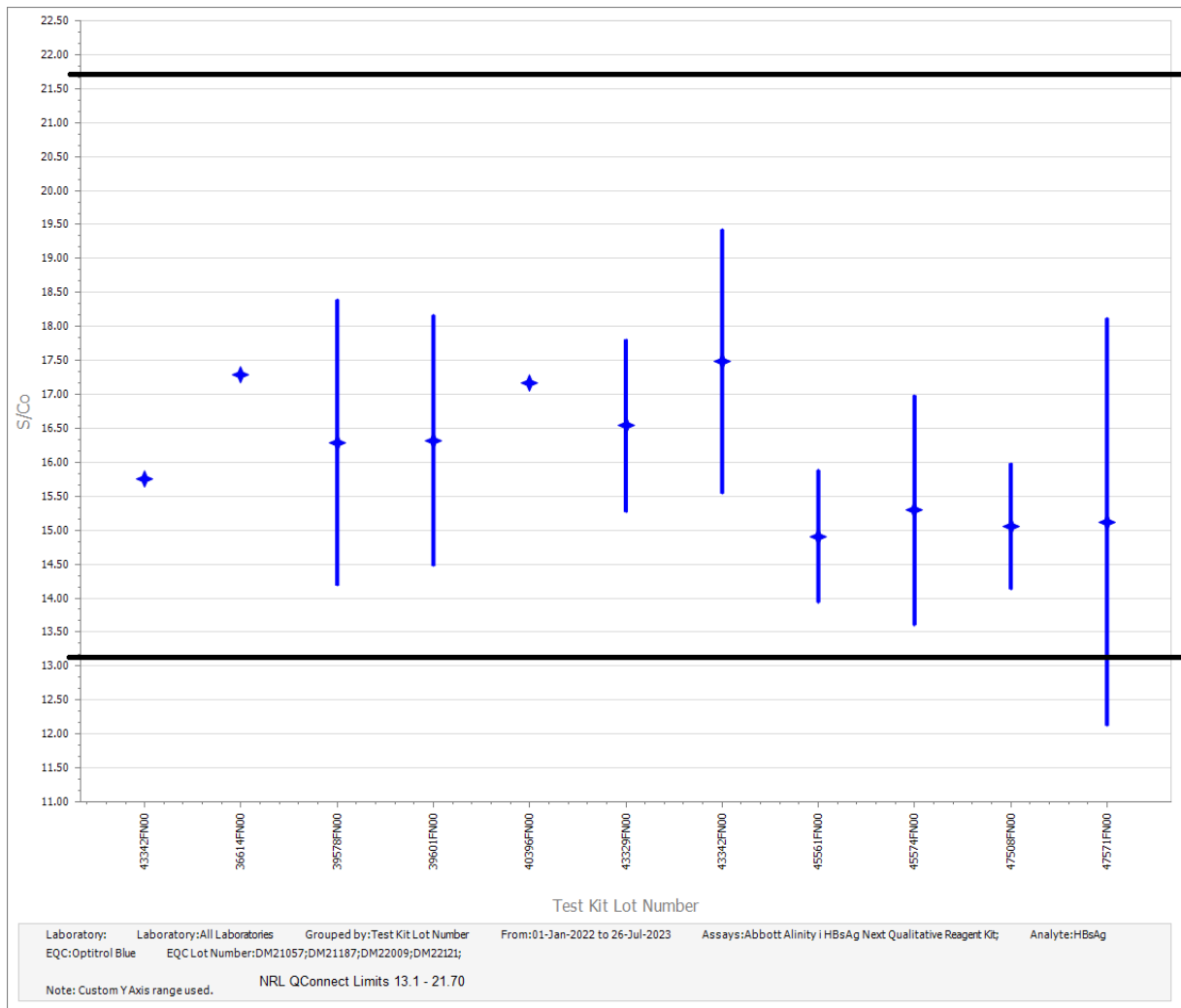


Figure 16. Peer group data for Optitrol Blue lots DM21057, DM21187, DM22009 and DM22121 when tested on the Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay by reagent lot and mean.

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
39578FN00	5	17.54	NA	NA	NA	17.11	18.11	NA
39601FN00	164	16.68	0.93	14.81	18.55	14.13	18.80	5.60
40396FN00	4	16.95	NA	NA	NA	16.57	17.56	NA
43342FN00	624	17.77	0.83	16.11	19.43	14.70	20.39	4.67
45574FN00	983	15.28	0.84	13.60	16.97	12.69	18.61	5.52
47508FN00	76	15.09	0.45	14.19	15.98	14.17	16.08	2.96
47571FN00	81	15.09	1.53	12.03	18.15	10.85	18.18	10.14
Totals	1937	16.20	1.45	13.30	19.09	10.85	20.39	8.95

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Test Kit Lot Number

From: 01-Jan-2022 to 26-Jul-2023

Assays: Abbott Alinity i HBsAg Next Qualitative Reagent Kit

Analyte: HBsAg

EQC: Optitrol Blue

EQC Lot Number: DM22009;

NA = Not enough data to compute standard deviation

Table1. Peer group data for Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue DM22009 by reagent lot.

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
43342FN00	1	15.76	NA	NA	NA	15.76	15.76	NA
36614FN00	7	17.30	NA	NA	NA	16.71	17.86	NA
39578FN00	127	16.29	1.05	14.19	18.40	14.28	18.66	6.46
39601FN00	491	16.32	0.92	14.48	18.17	14.13	19.31	5.66
40396FN00	5	17.17	NA	NA	NA	16.57	18.06	NA
43329FN00	89	16.54	0.64	15.27	17.81	15.15	17.98	3.85
43342FN00	955	17.49	0.97	15.54	19.43	14.70	22.35	5.56
45561FN00	71	14.91	0.49	13.94	15.89	14.07	16.35	3.27
45574FN00	997	15.30	0.85	13.61	16.99	12.69	18.61	5.53
47508FN00	79	15.06	0.46	14.13	15.99	14.00	16.08	3.08
47571FN00	85	15.12	1.50	12.12	18.12	10.85	18.18	9.92
Totals	2907	16.26	1.33	13.59	18.92	10.85	22.35	8.20

Legend:

Laboratory:

Laboratory: All Laboratories

Grouped by: Test Kit Lot Number

From: 01-Jan-2022 to 26-Jul-2023

Assays: Abbott Alinity i HBsAg Next Qualitative Reagent Kit;

Analyte: HBsAg

EQC: Optitrol Blue

EQC Lot Number: DM21057;DM21187;DM22009;DM22121;

NA = Not enough data to compute standard deviation

Table2. Peer group data for Abbott Alinity i HBsAg Next Qualitative Reagent Kit assay with Optitrol Blue lots DM21057, DM21187, DM22009 and DM22121 by reagent lot.