

# **QC Services Investigation: PMM-QC-2025**

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Report prepared by: Kylie Davies

Authorised By: Joe Vincini

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## INTRODUCTION

Participant 1860 contacted NRL regarding a shift up in data observed for Optitrol Blue lot DM23117 when testing with the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00. NRL investigated all data reported by the peer group and those participants testing with reagent lot 60107BE00 in combination with other related production lots of Optitrol Blue, Abbott Alinity i rHTLV-I/II reagent 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 combination identified by Participant 1860 and any other Optitrol Blue lot with data reported to EDCNet using the reagent lot in question (60107BE00), to establish whether reagent lot variation was the source of variation observed. Below is the full listing of charts and tables included in the investigation:

- Figure 1 – Participant 1860 Levy Jennings chart grouped by reagent lot illustrating a shift up in data for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00.
- Figure 2 – Participant 1860 peer group chart grouped by reagent lot illustrating Participant 1860 data were reported consistent with peer group data for four reagent lots in common usage, including 60107BE00.
- Figure 3– Participant 1860 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
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- Figure 10 – Participant 58 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 11 – Participant 451 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23204 when testing on the Abbott Alinity i rHTLV-I/II assay.
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- Figure 14 – Participant 1321 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 15 – Participant 1353 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
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- Figure 36 – Participant 1891 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 37 – Participant 1891 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
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- Figure 40 – Participant 1747 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 41 – Participant 1747 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 42 – Participant 1945 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 43 – Participant 1945 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 44 – Participant 1744 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 45 – Participant 1744 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 46 – Participant 1566 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.
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- Figure 48 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Anti-HCV II assay sorted by reagent lots.
- Figure 49 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i HBsAg Qualitative II assay sorted by reagent lots.
- Figure 50 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i HIV Ag/Ab Combo assay sorted by reagent lots.
- Figure 51 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Syphilis TP assay sorted by reagent lots.

- Figure 52 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Anti-HBc II assay sorted by reagent lots.
- Figure 53 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity s Anti-HTLV I/II assay sorted by reagent lots.
- Figure 54 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott ARCHITECT rHTLV-I/II assay sorted by reagent lots.

## DISCUSSION

Figures 1 through 5 each show data for both Participant 1860 and the peer group that demonstrates anti-HTLV-I marker performance for Optitrol Blue lot DM23117, when tested with the Abbott Alinity i rHTLV-I/II assay. Reagent lot 60107BE00 data were reported by Participant 1860 at a higher S/Co value than previous reagent lots and several data points were reported above the upper QConnect Limit (S/C 1.50 – 2.30). Peer group data appeared consistent with data reported by Participant 1860 although the degree of the shift observed was notably different across the peer group, as seen in Figures 4 and 5.

Figures 6 through 39 show each individual participant data for Optitrol Blue DM23117 and related production lots (DM23204 and DM24063) and, where reported, the Positive Kit Control when tested on the Abbott Alinity i rHTLV-I/II assay. All but two participants (Participants 25 and 1353) reported Positive Kit Control data to EDCNet. The same shift observed for Participant 1860 was observed across all but five participants across the peer group for both Optitrol Blue and positive kit control data. No shift was observed for Participants 1562, 1689, 1750, 1870 and 1892 for data reported for reagent lot 61017BE00, data for those participants were consistent and within QConnect Limits. Additional shifts observed for Positive kit control data were likely due to new lots of kit control in use. This was noted in EDCNet by several participants and appears to have no correlation to the shift investigated for this report.

Figures 40 through 49 show participant data for Participants 1747, 1945, 1744 and 1566 related to Optitrol Blue lot DM23117 when tested on the Abbott Alinity i rHTLV-I/II assay. These four participants did not use reagent lot 6017BE00. The same shift observed for reagent lot 6017BE00 was observed for reagent lots 62294BE00 and 60108BE00.

Nine participants, including 1860 (451, 1732, 1748, 1891, 1747, 1945, 1744 and 1566) were identified as participants where data showed a larger shift than that observed across the peer group. Four of these participants (451, 1732, 1945 and 1744) reported this shift within the use of a single Optitrol and reagent lot for each participant. Two of these participants (451 and 1744) reported a shift back to expected values (see Figures 11, 12, 44 and 45, respectively).

Figures 48 through 52 show peer group data for Optitrol Blue lot DM23117 and related production lots DM23204 and DM24063 when tested with the other Abbott Alinity i assays. No shift was observed.

Figures 53 and 54 show peer group data for Optitrol Blue lot DM23117 and related production lots DM23204 and DM24063 when tested with the Abbott Alinity s Anti-HTLV I/II and Abbott ARCHITECT rHTLV-I/II. No shift was observed.

NRL contacted all participants within the Abbott Alinity i rHTLV-I/II peer group, either directly or indirectly through Optitrol distributor networks, requesting information on maintenance, calibration lots and status. Communications received from the peer group identified the nine participants previously identified as reporting a higher than peer group shift were all using calibrator lot 61765BE00. The remaining participants were using several different calibrator lots.

Participant 451 communicated to NRL the use of calibrator lot 61765BE00 for data reported while testing with Optitrol Blue DM23204 and reagent lot 60107BE00 from 1 August 2024. All data were reported above the upper QConnect limit of 2.30 S/Co. The participant noted a calibration was performed on the 16 August 2024 using calibrator lot 64503BE00, subsequent data were reported at lower values consistent with peer group data and within QConnect limits, as illustrated in Figure 11.

Participant 1744 noted in EDCNet the use of calibrator lot 61765BE00, on the 25 September 2024, after which a shift up was observed. The participant recalibrated with a previously used calibrator lot, 60066BE00, on the 27 September 2024, subsequent data returned to lower values consistent with historical data and within QConnect limits, as illustrated in Figure 44.

NRL contacted Abbott GmbH Germany with these findings, requesting information on calibrator lot 61765BE00 and if this shift was expected and whether this was expected to be an ongoing shift. Abbott communicated to NRL that a shift was observed within internal testing for the HTLV calibrator 61765BE00, potentially caused by a slightly lower RLU signal for this calibrator lot. It was communicated to NRL that it was unlikely that the raised level would continue, and levels were expected to return to lower levels for future lots. Importantly, all data were within Abbott release specification criteria.

## CONCLUSIONS

The shift up in S/Co value observed by Participant 1860 Optitrol Blue lot DM23117 when testing with the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00 was a result of calibrator lot variation. This was also observed for Optitrol Blue DM23204 and reagent lots 62294BE00 and 60108BE00 across the peer group when calibrator lot 61765BE00 was reported in use. As communicated by Abbott this is unlikely to be observed in subsequent calibrator lots.

## RECOMMENDATIONS

NRL recommends participants notify NRL QC Services at the introduction of calibrator lot 61765BE00.

NRL recommends participants monitor these data using the laboratory limits set by NRL as provided in EDCNet. These laboratory limits calculations include only data reported to EDCNet for calibrator lot 61765BE00.

NRL recommends participants contact their Abbott representative if they have any questions or concerns regarding any potential clinical sensitivity implications.

NRL will continue to monitor Abbott Alinity i rHTLV-I/II assay.

NRL will continue to review Laboratory Limits set in EDCNet for data report under calibration using calibrator lot 61765BE00 and communicate these to the peer group weekly.

For more information, please contact NRL at [qconnect@nrlquality.org.au](mailto:qconnect@nrlquality.org.au).



# APPENDIX

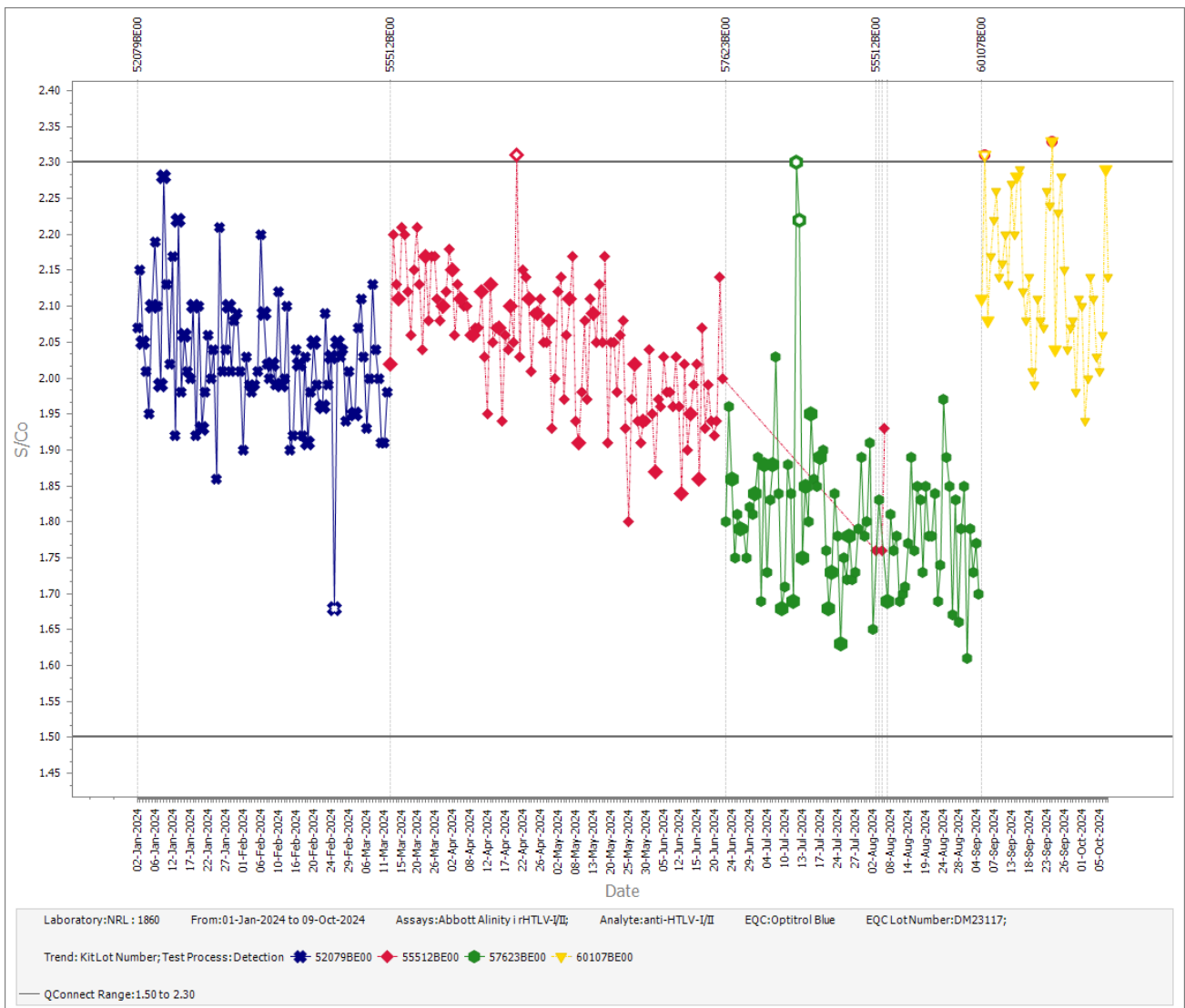


Figure 1 – Participant 1860 Levy Jennings chart grouped by reagent lot illustrating a shift up in data for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00.

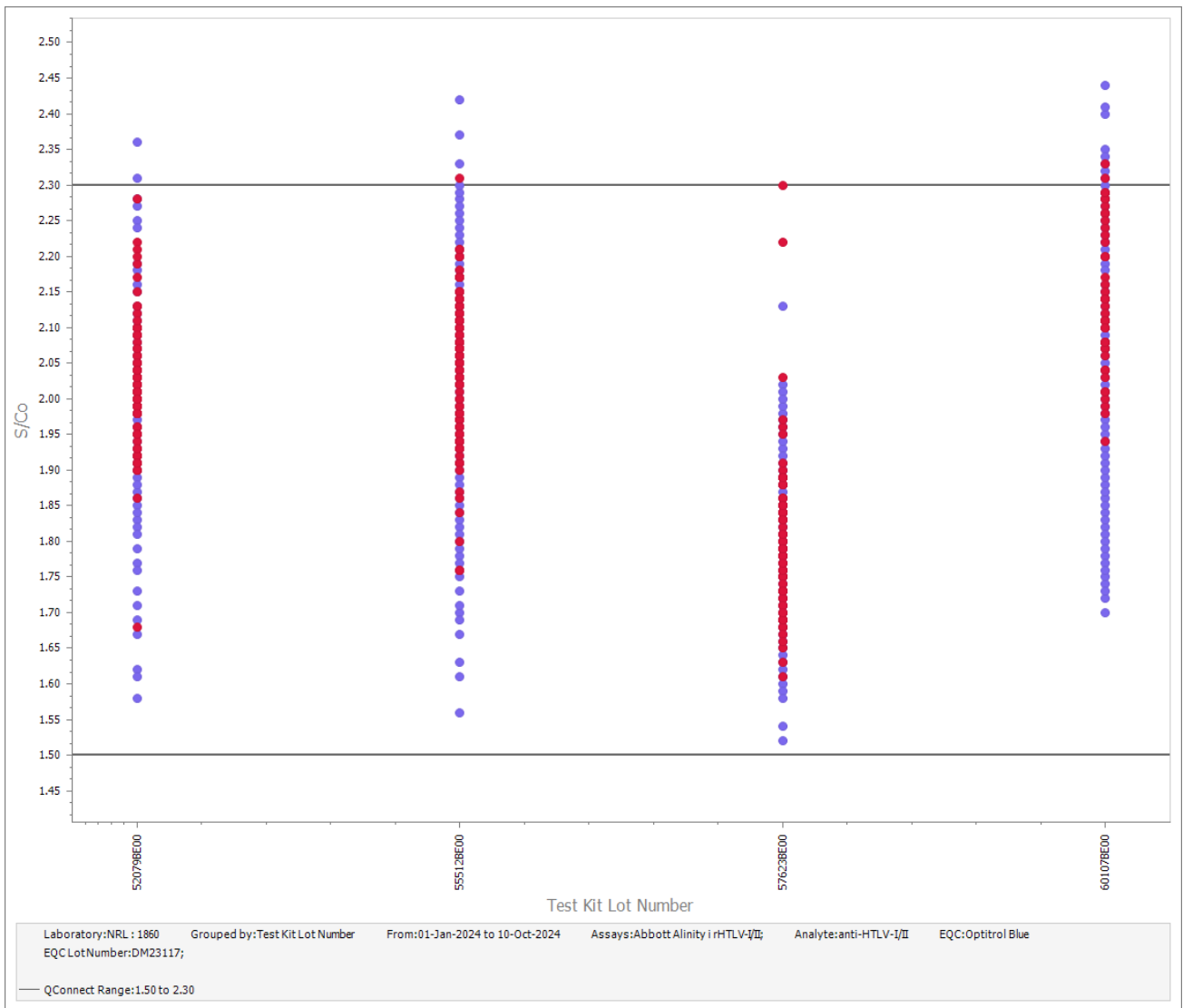


Figure 2 – Participant 1860 peer group chart grouped by reagent lot illustrating Participant 1860 data were reported consistent with peer group data for four reagent lots in common usage, including 60107BE00.

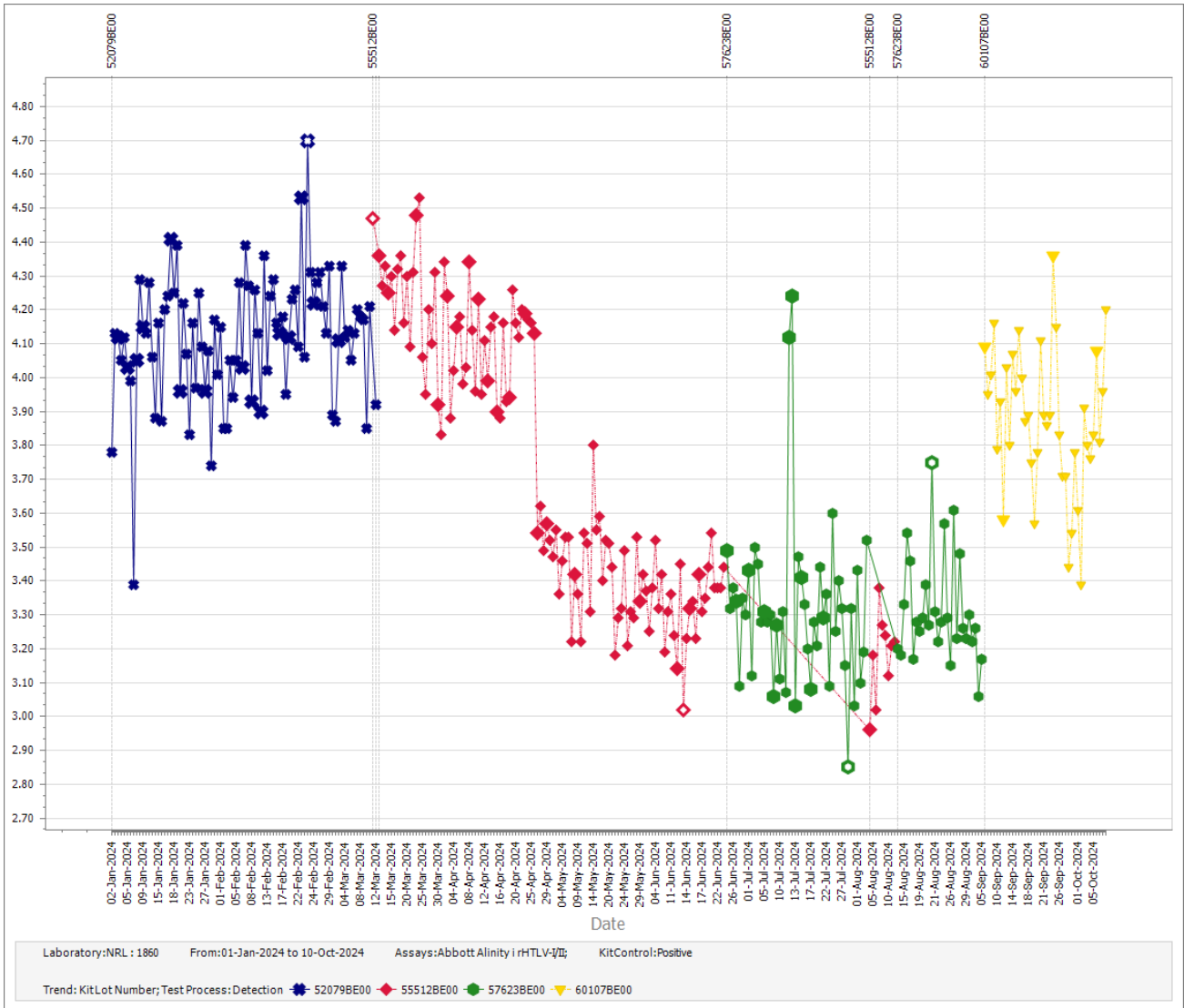


Figure 3 – Participant 1860 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

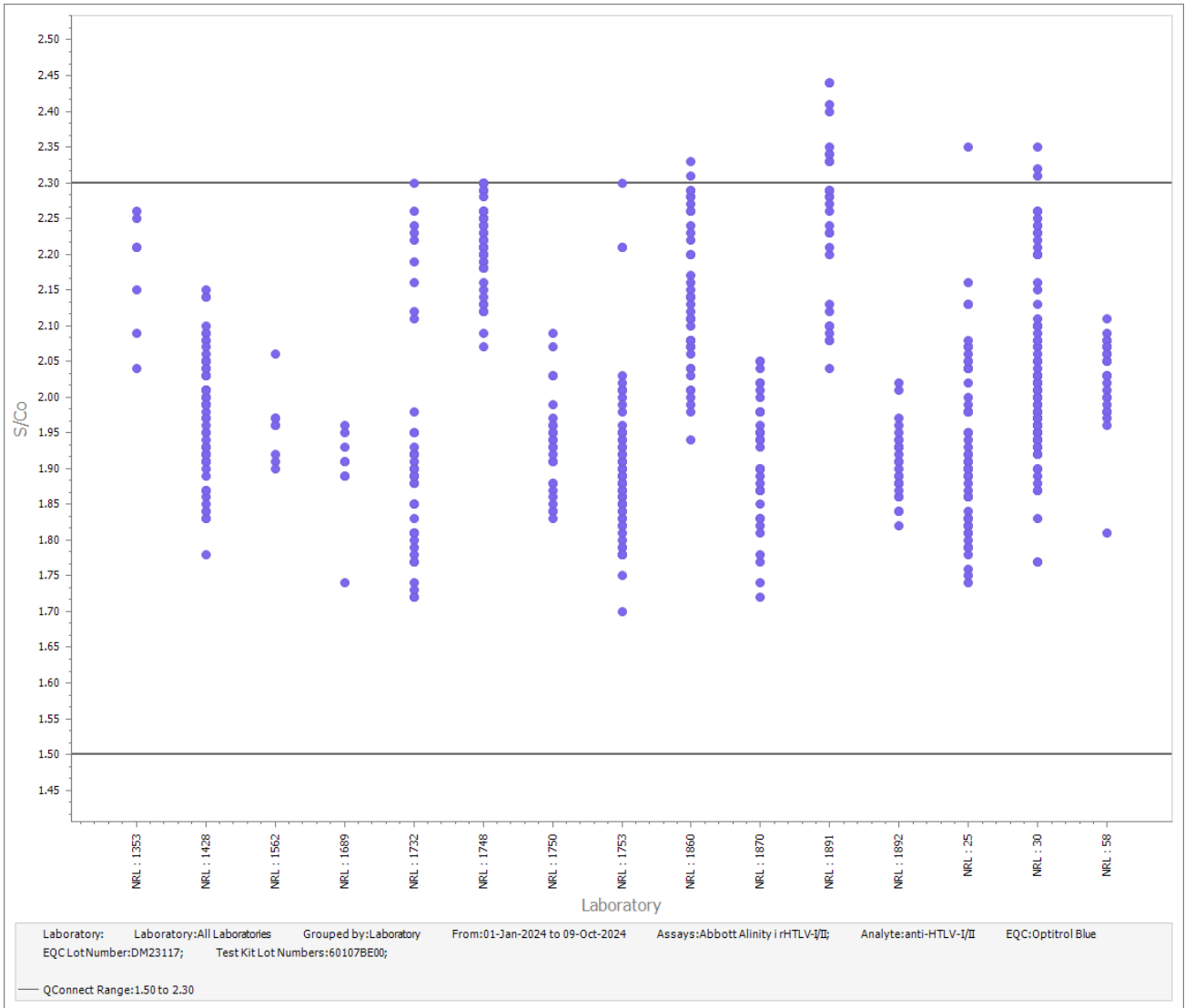


Figure 4 – Peer group data for Optitrol Blue lot DM23117 when tested on the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00 sorted by participants.

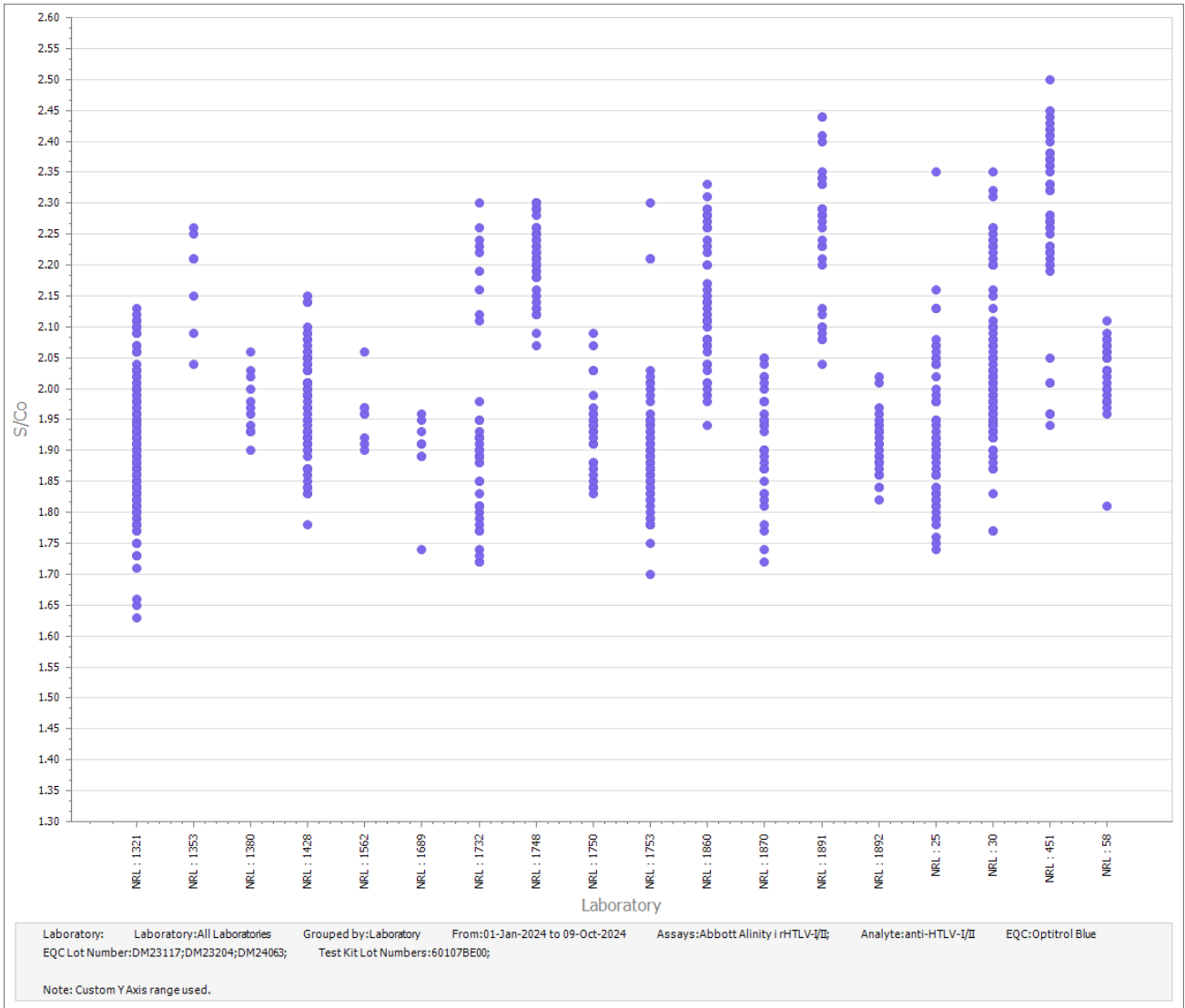


Figure 5 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on the Abbott Alinity i rHTLV-I/II assay for reagent lot 60107BE00 sorted by participants.

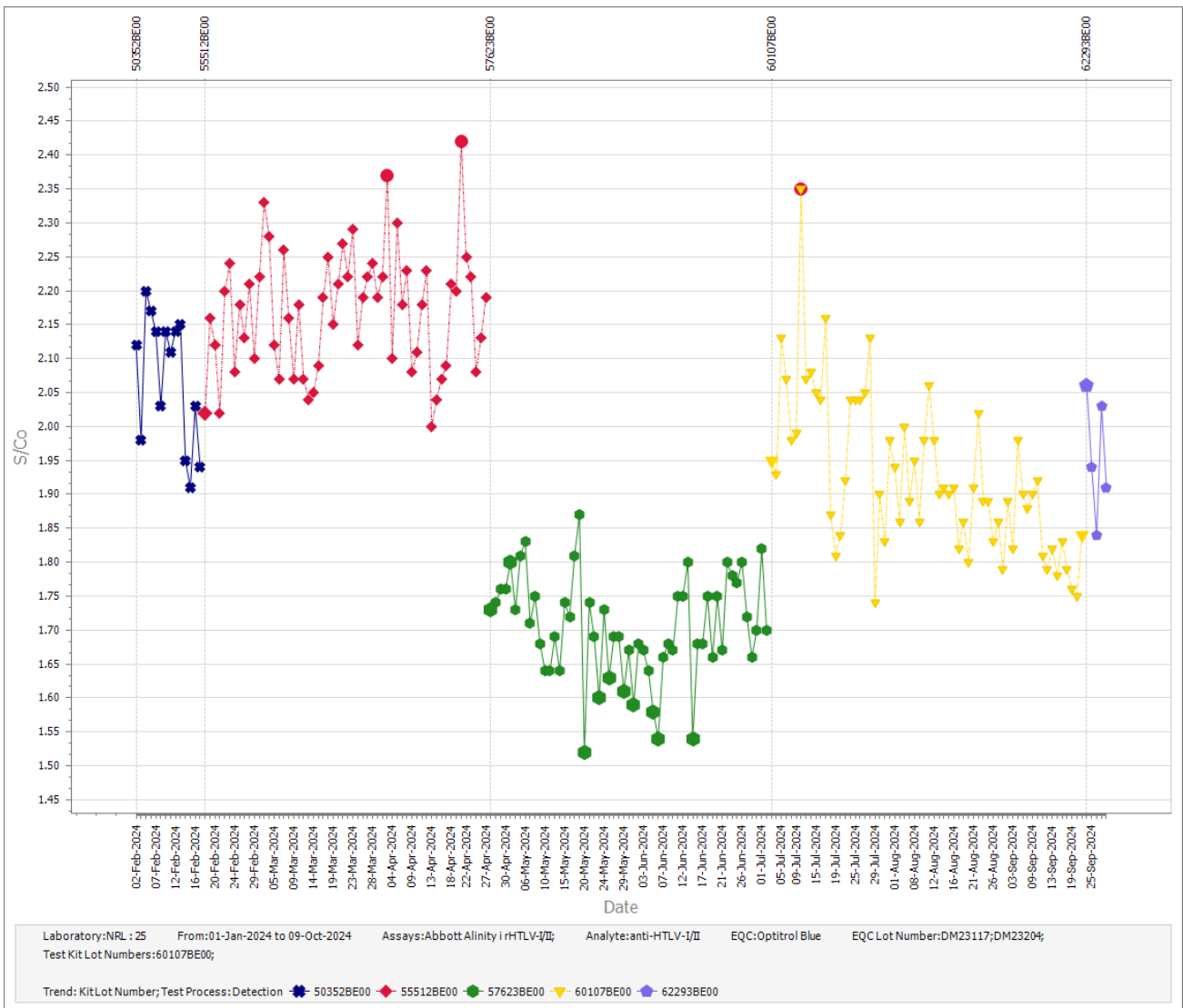


Figure 6 – Participant 25 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 & DM23204 when testing on the Abbott Alinity i rHTLV-I/II assay.

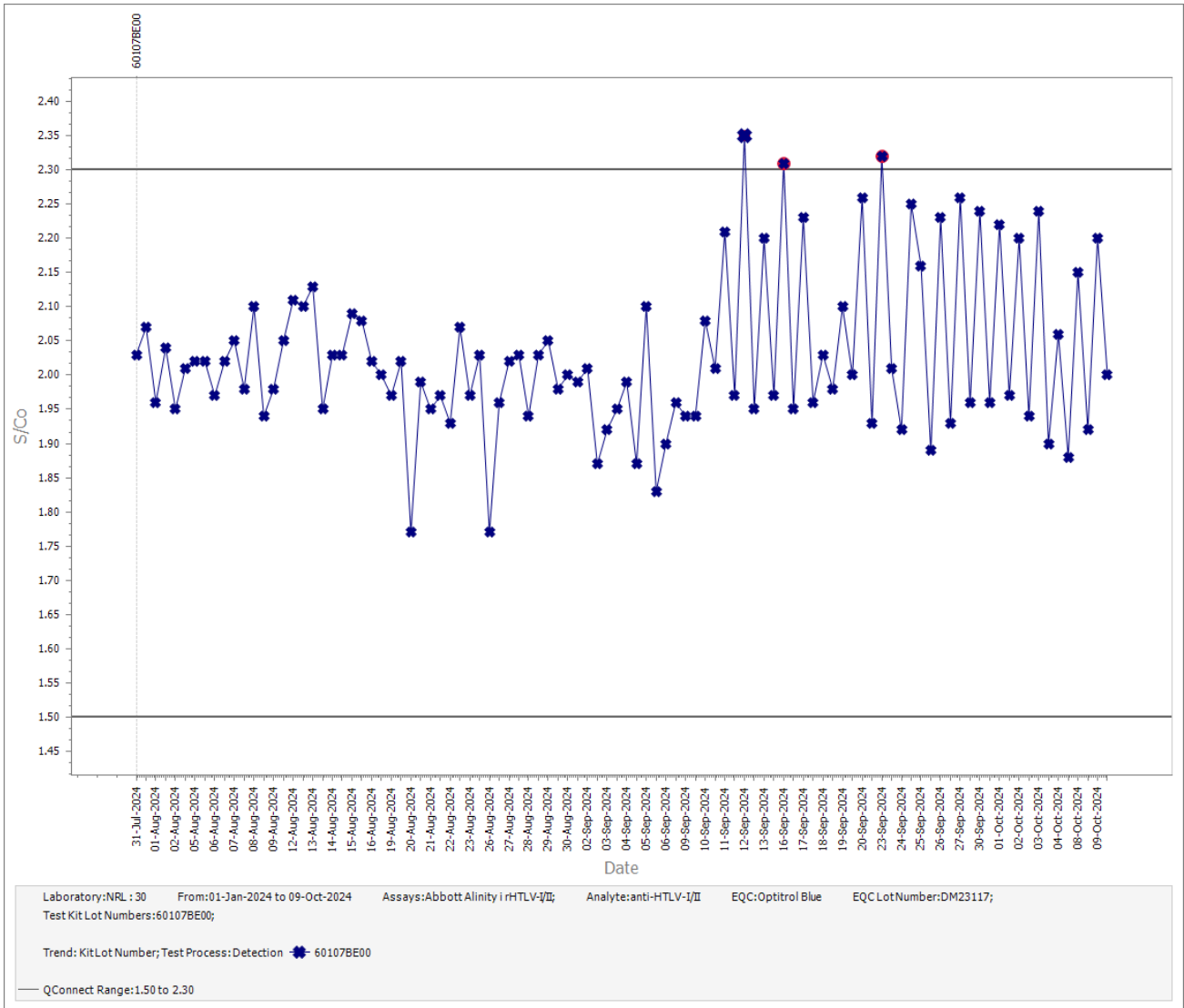


Figure 7 – Participant 30 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

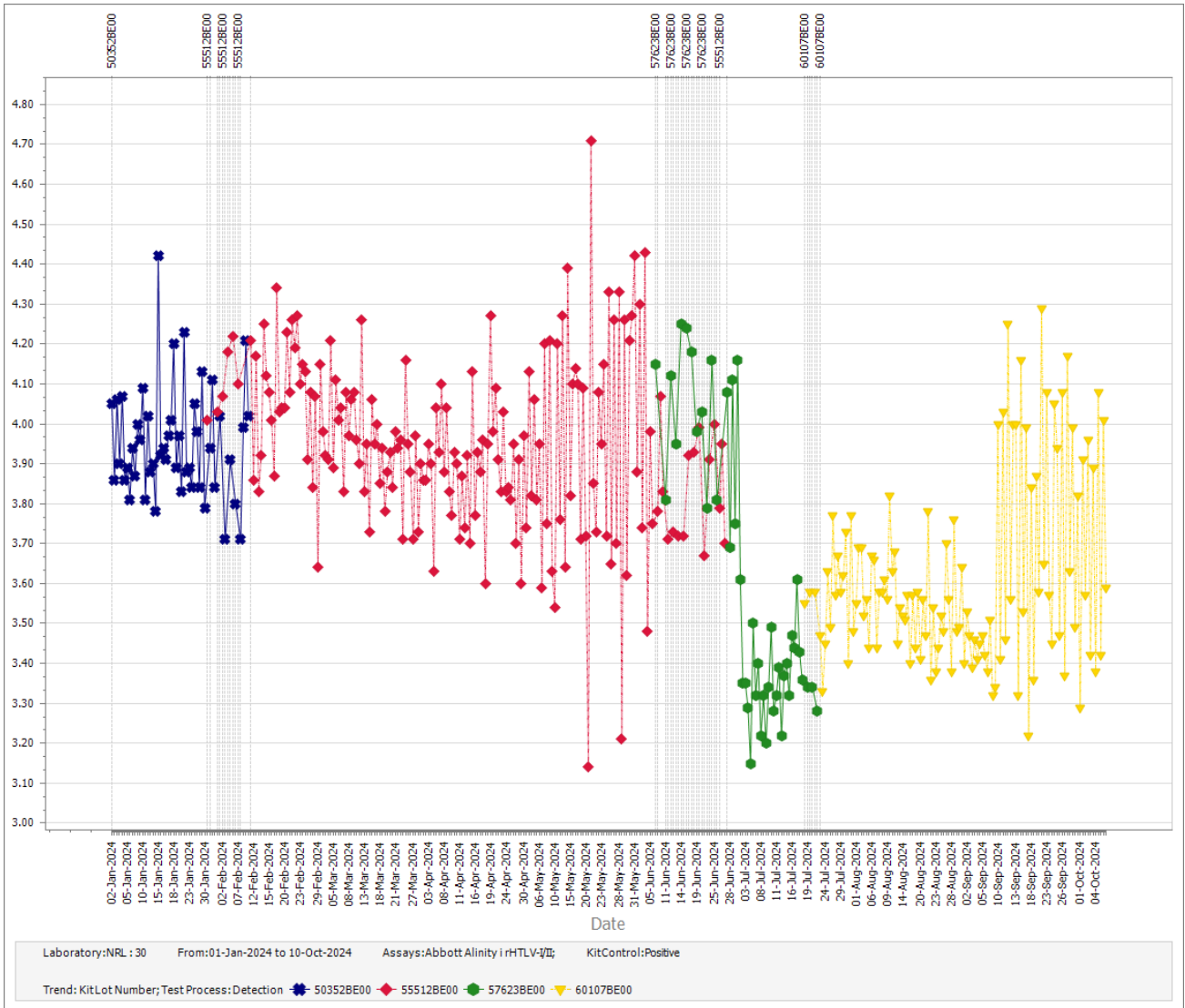


Figure 8– Participant 30 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.



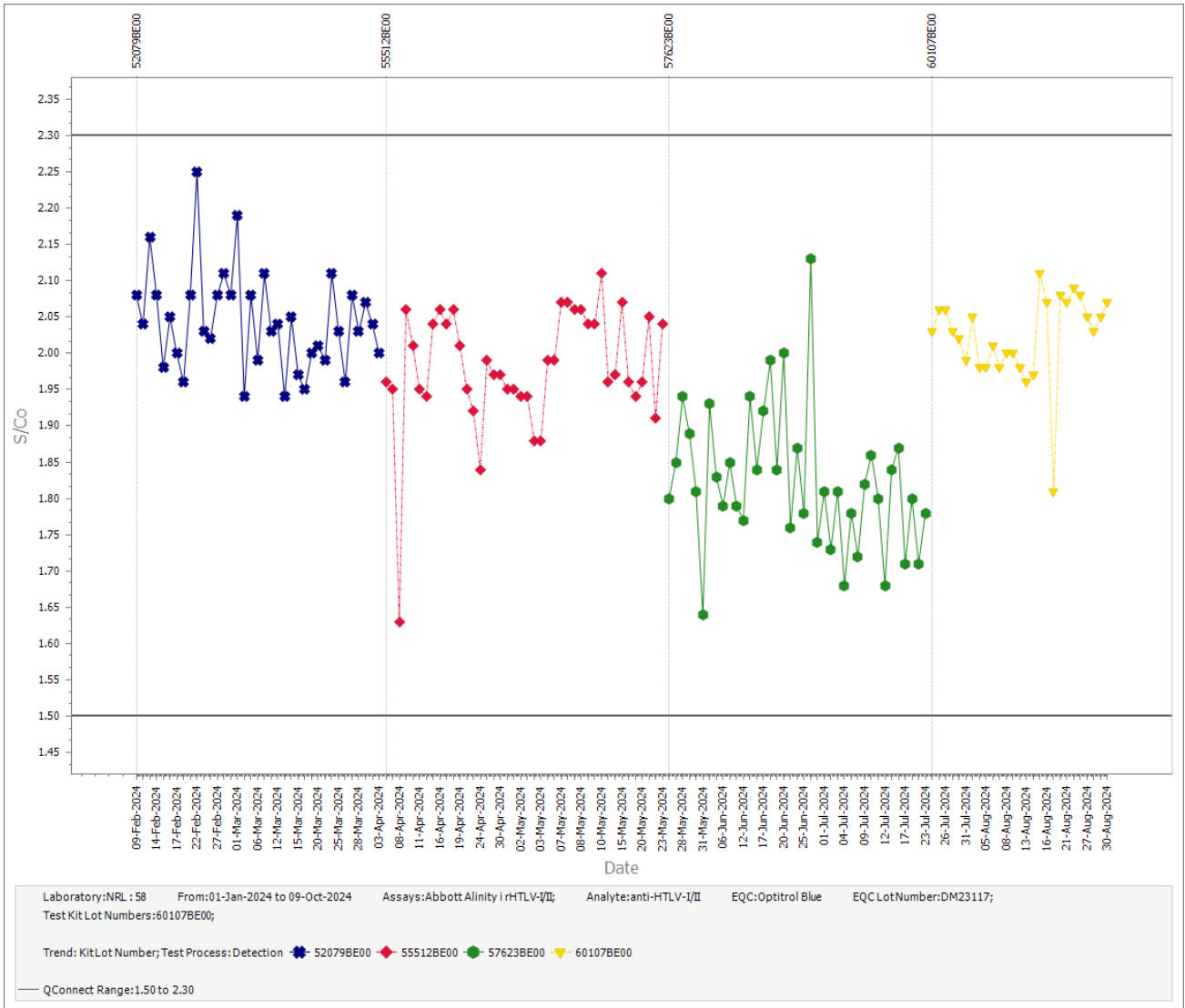


Figure 9 – Participant 58 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

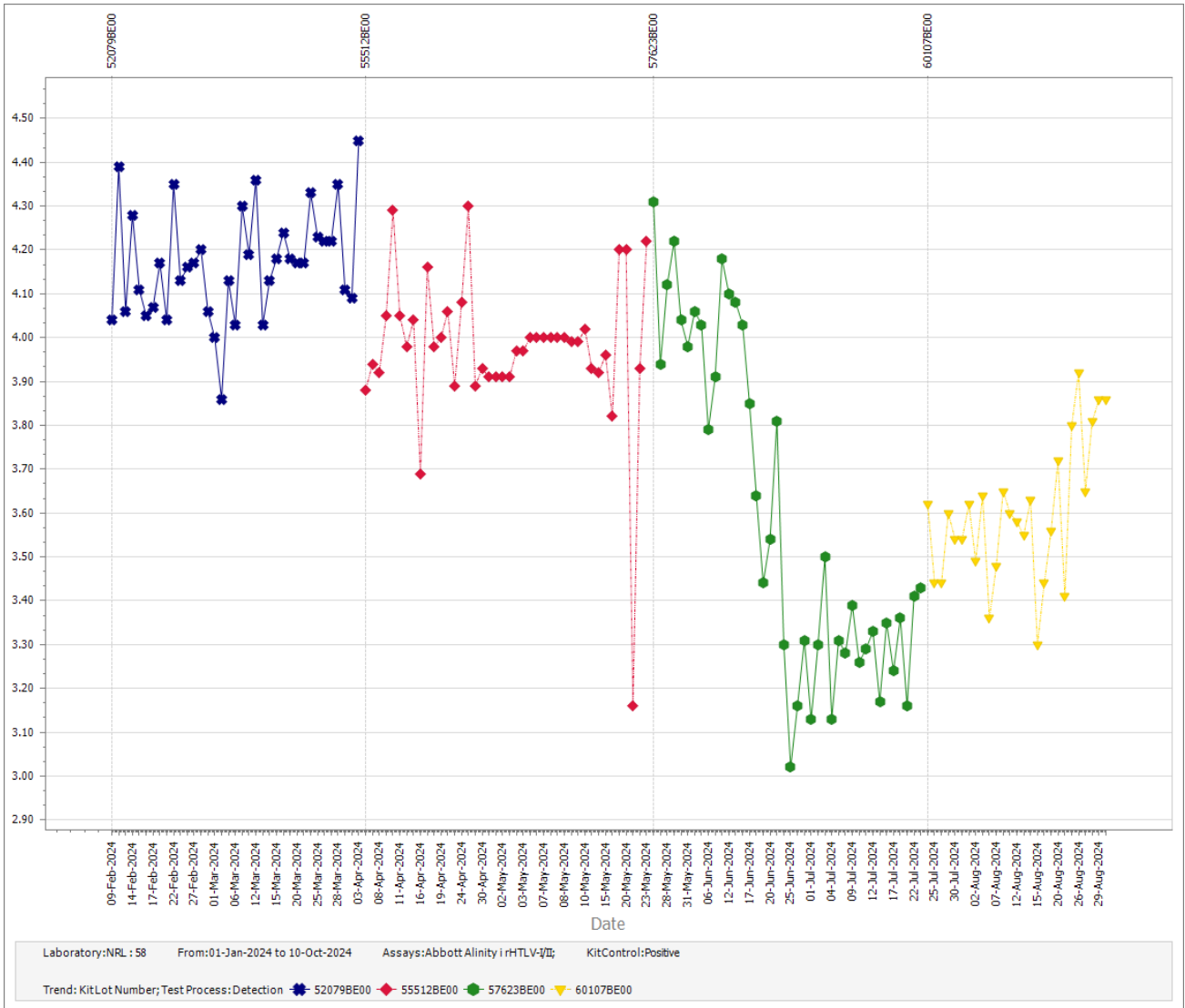


Figure 10 – Participant 58 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

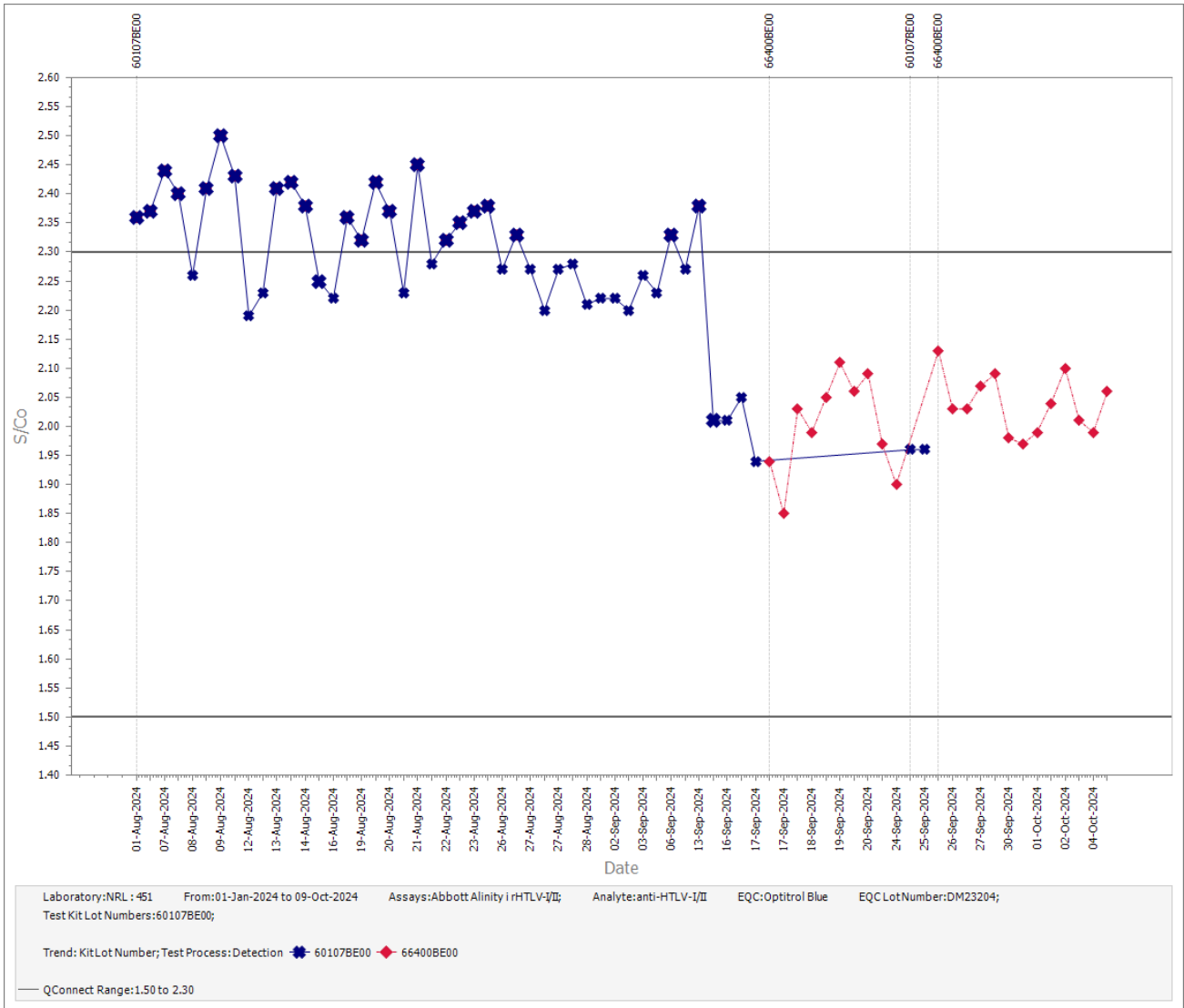


Figure 11 – Participant 451 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23204 when testing on the Abbott Alinity i rHTLV-I/II assay.

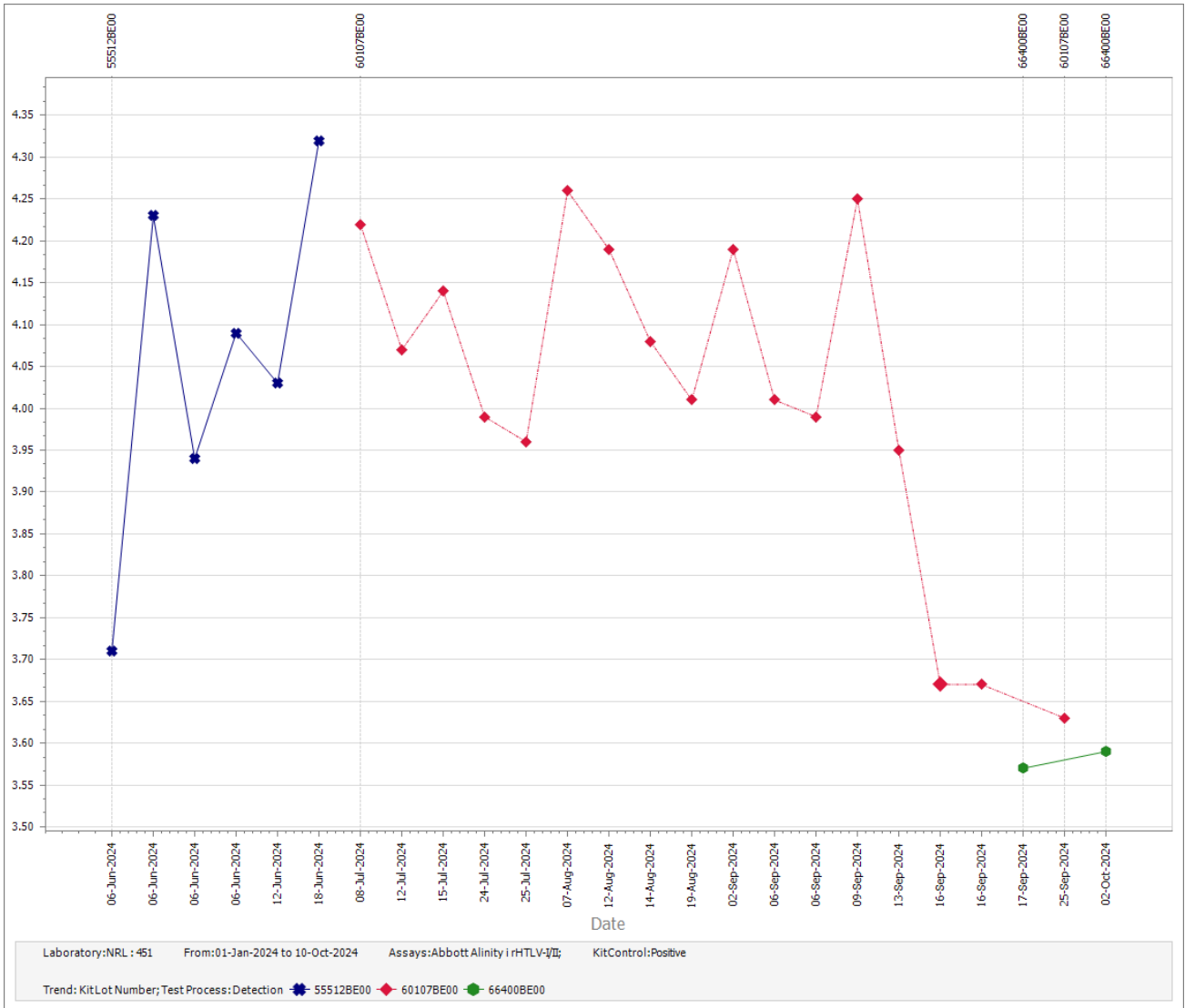


Figure 12 – Participant 451 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

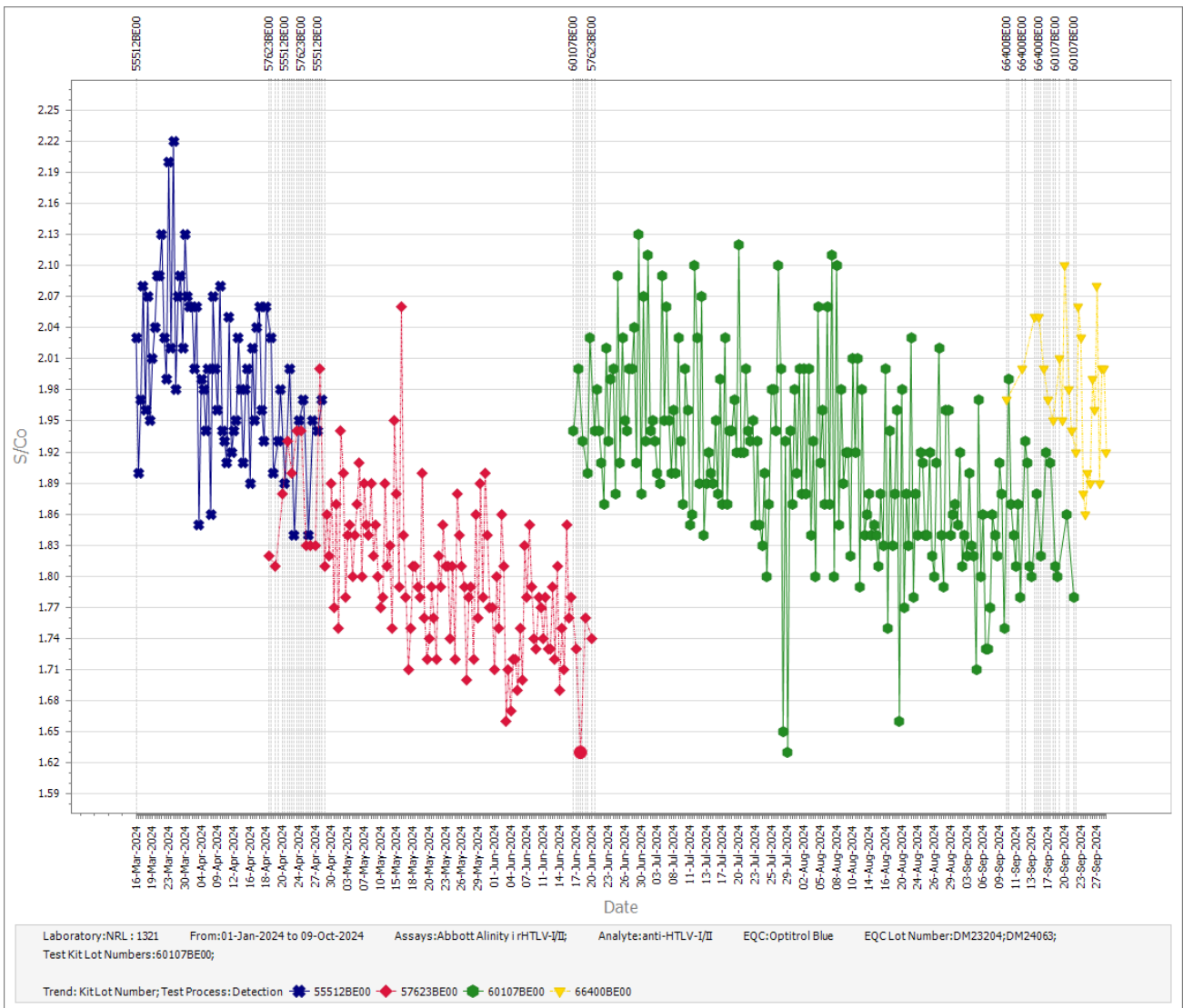


Figure 13 – Participant 1321 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23204 and DM24063 when testing on the Abbott Alinity i rHTLV-I/II assay.

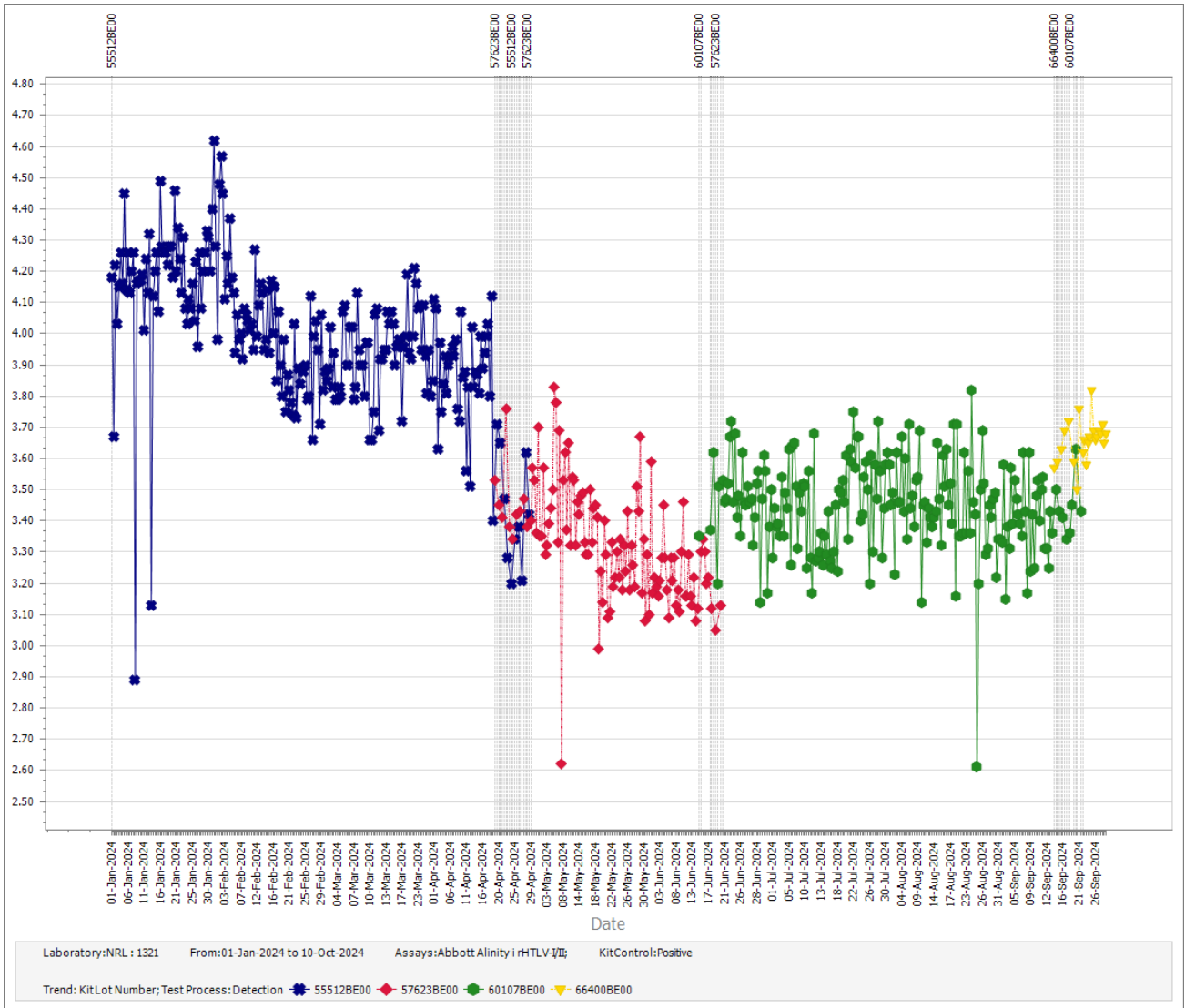


Figure 14 – Participant 1321 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

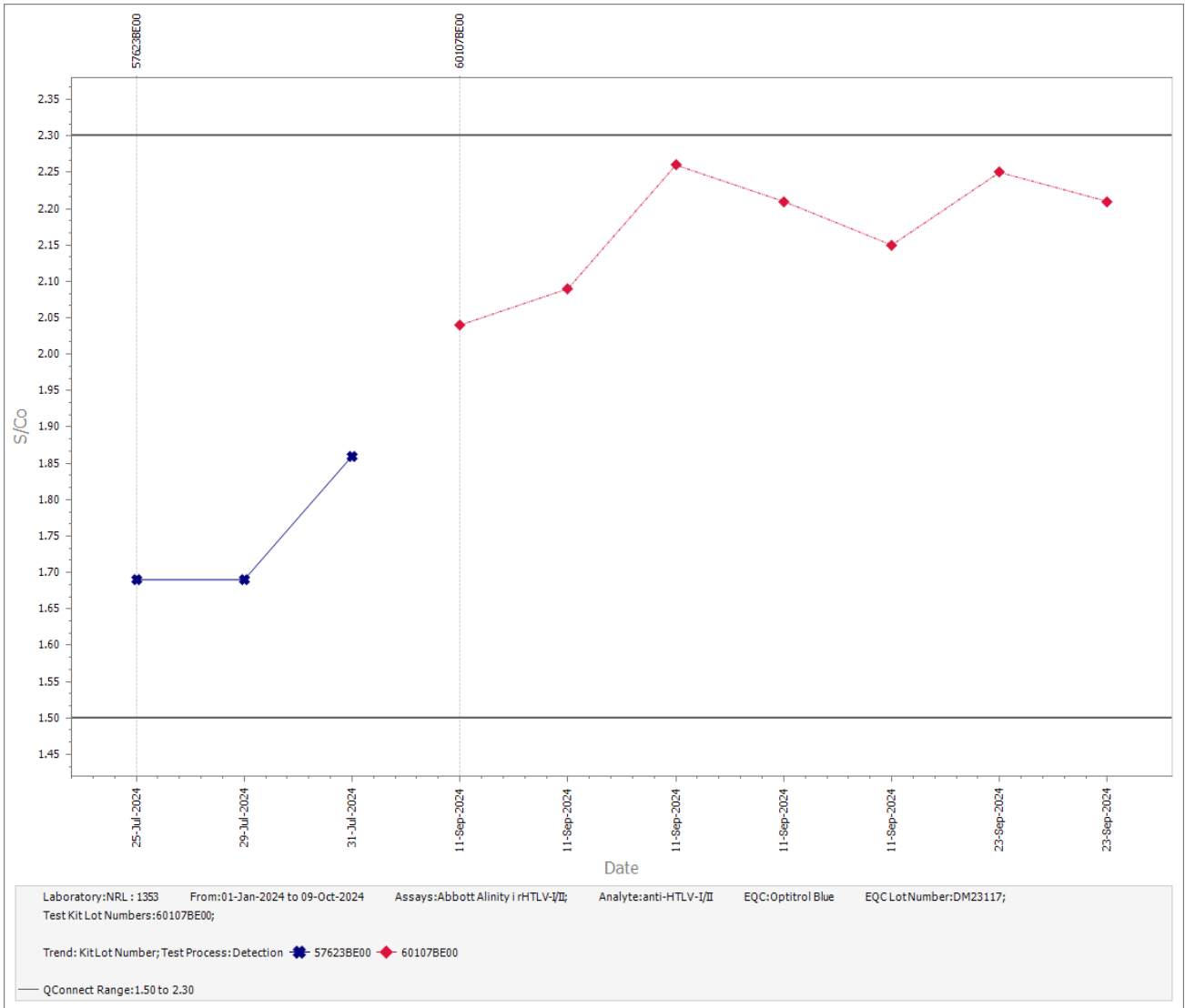


Figure 15 – Participant 1353 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

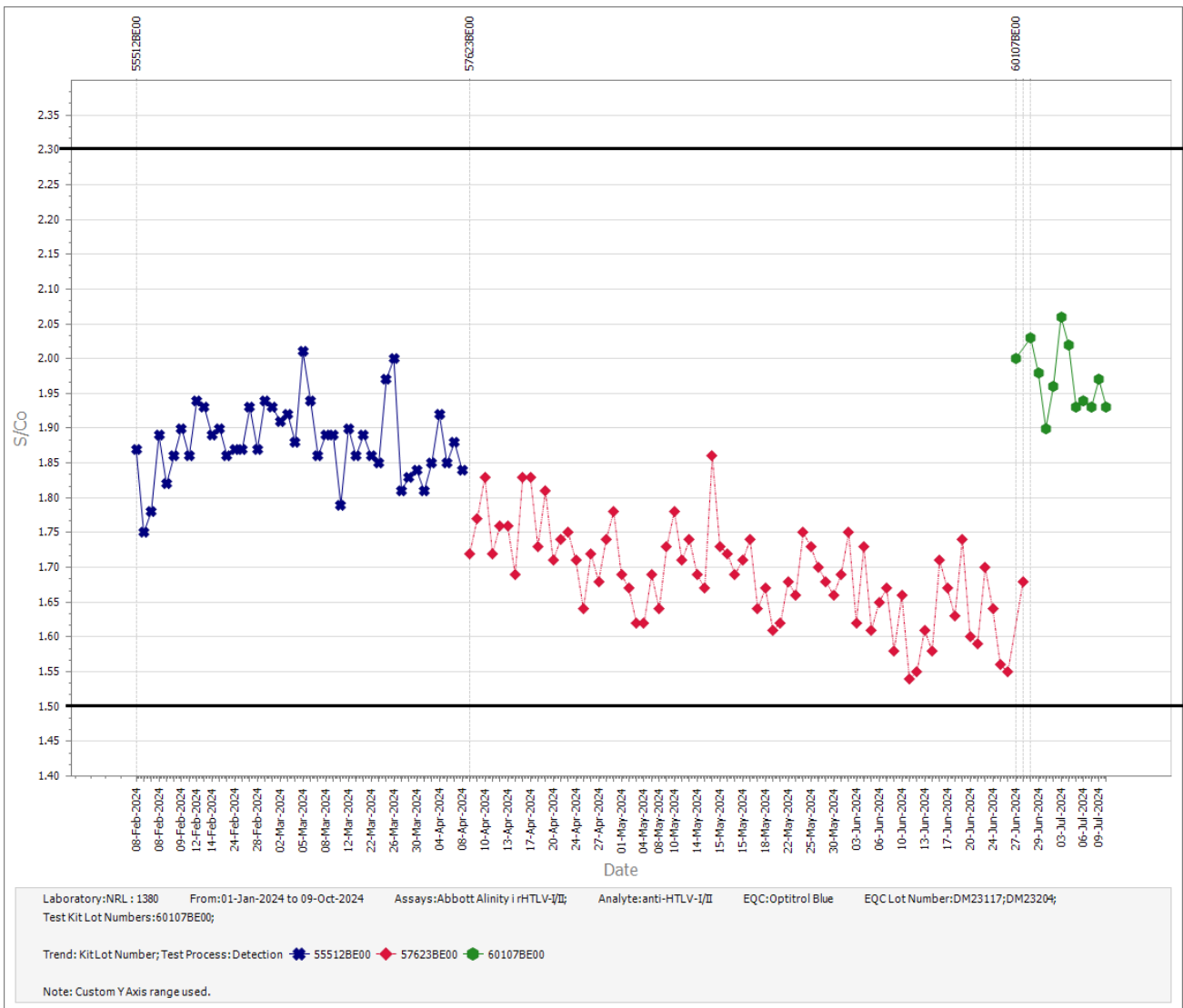


Figure 16 – Participant 1380 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 and DM23204 when testing on the Abbott Alinity i rHTLV-I/II assay.



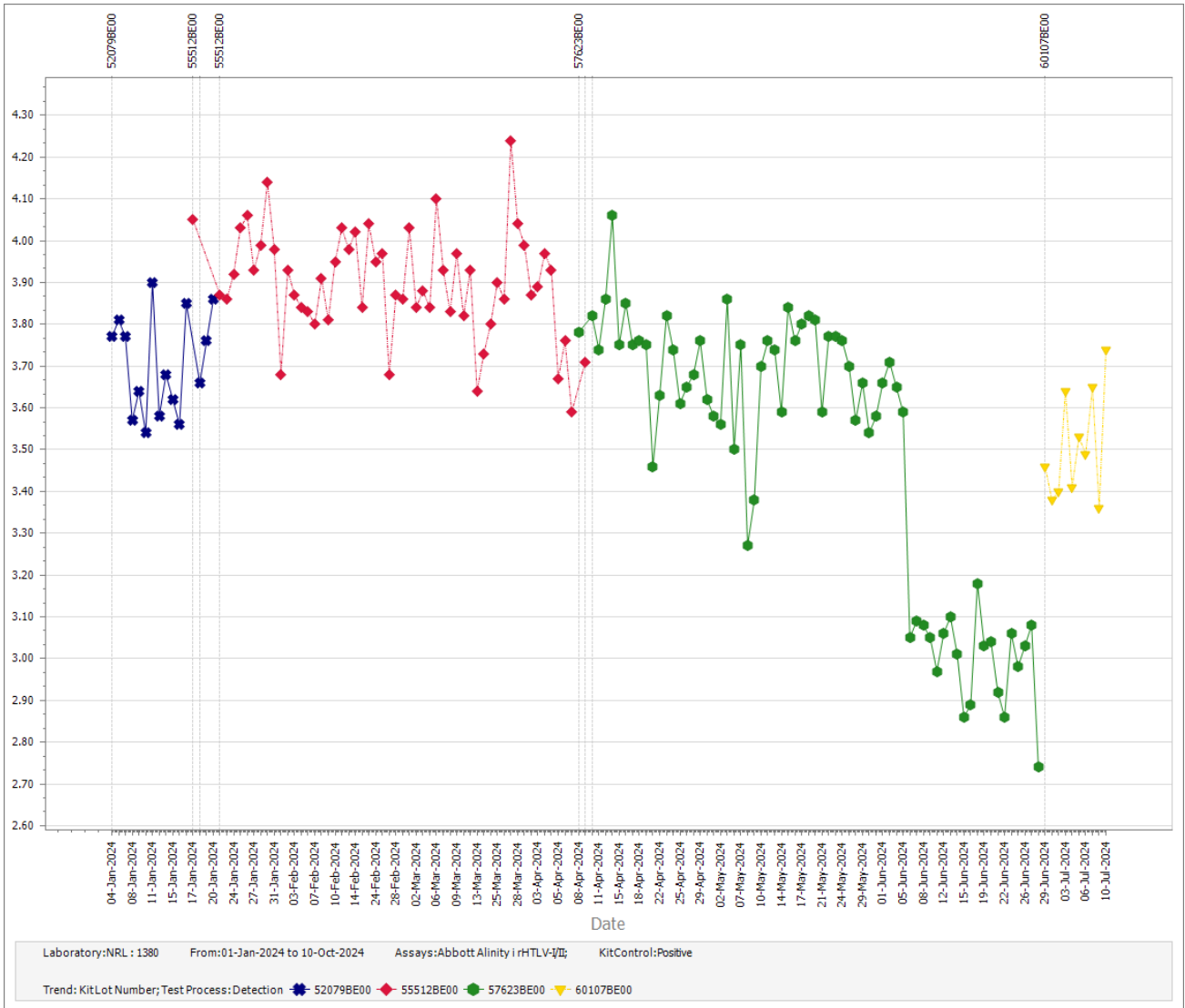


Figure 17 – Participant 1380 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

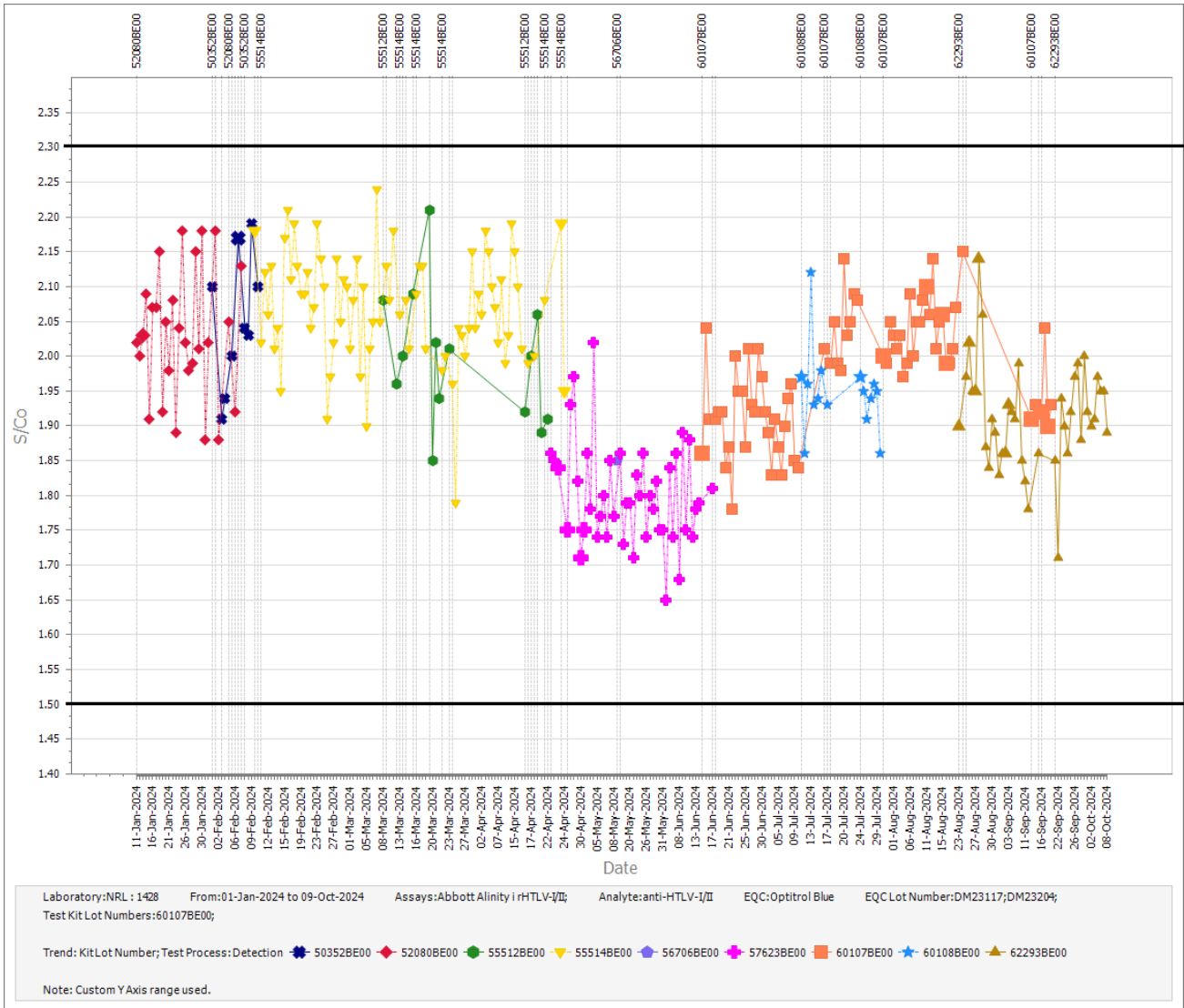


Figure 18 – Participant 1428 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 and DM23204 when testing on the Abbott Alinity i rHTLV-I/II assay.

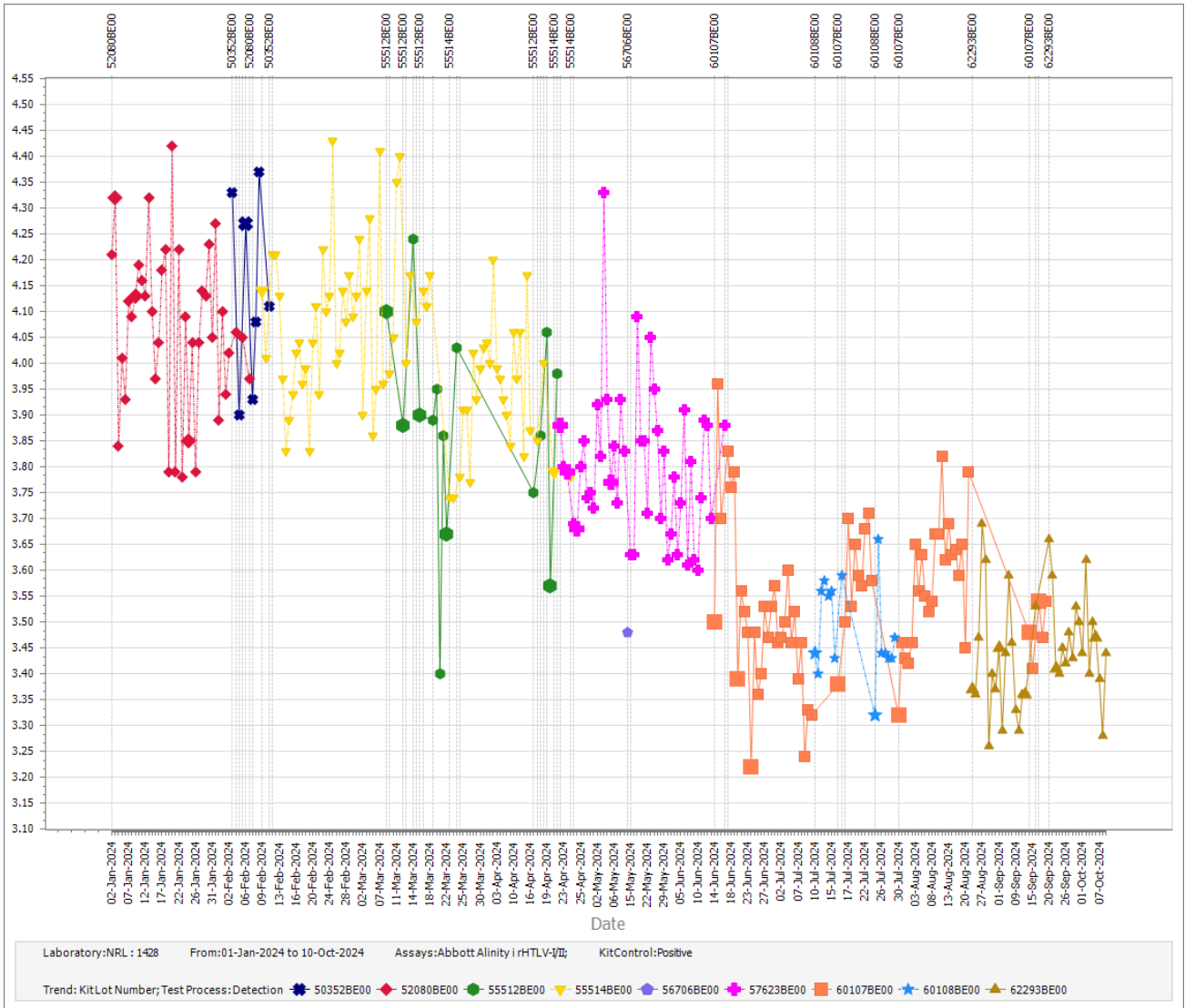


Figure 19 – Participant 1428 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

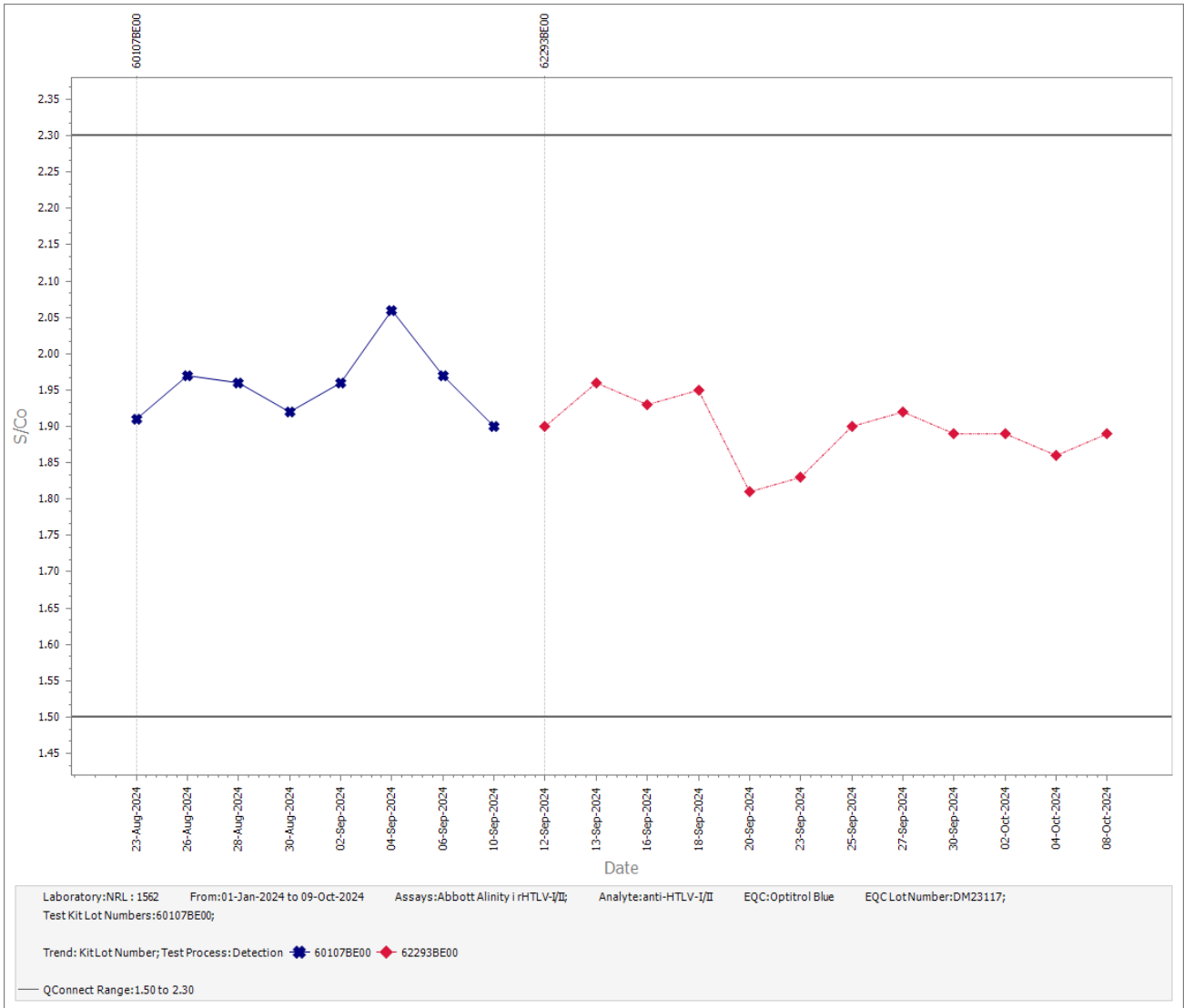


Figure 20 – Participant 1562 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

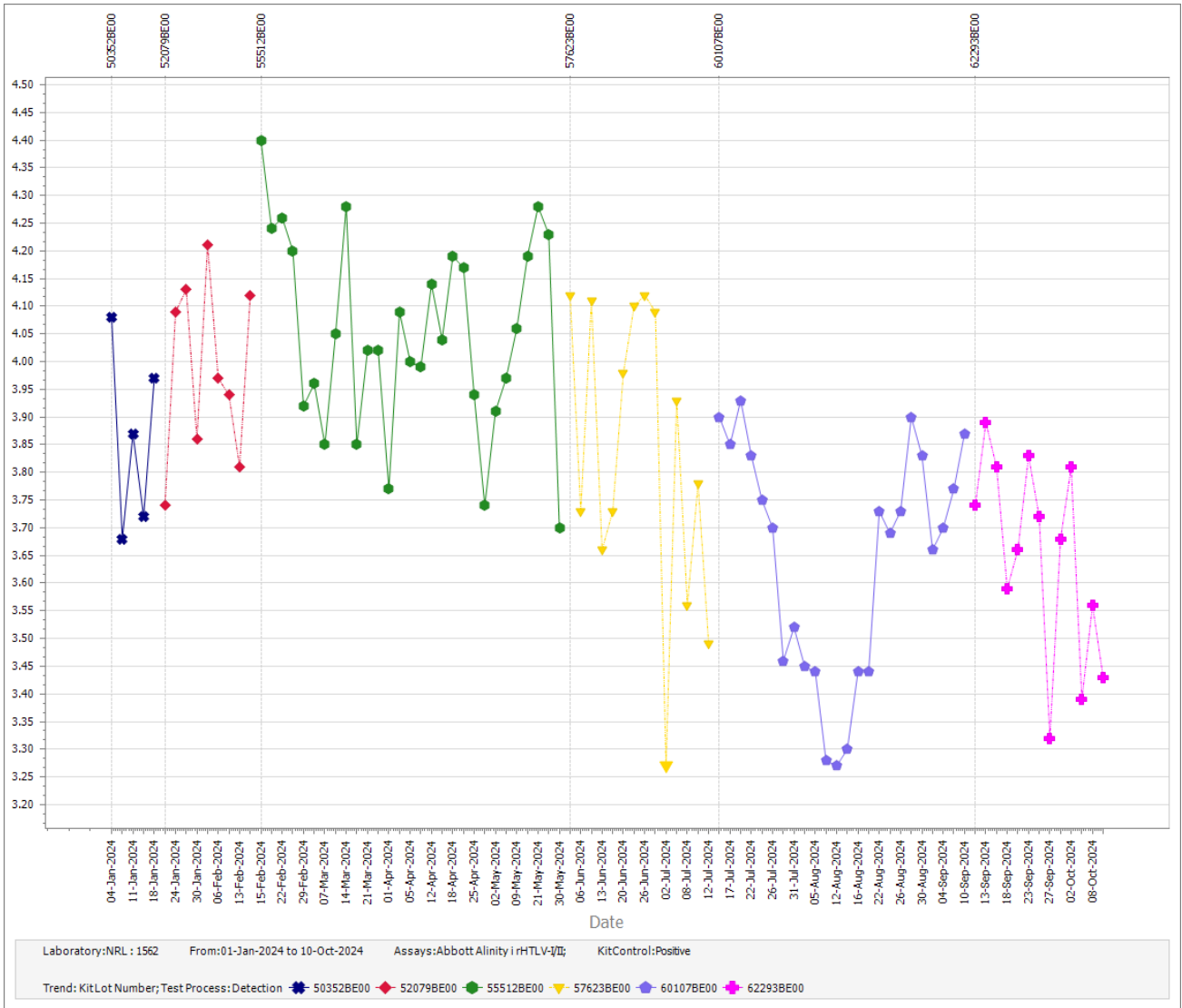


Figure 21 – Participant 1562 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

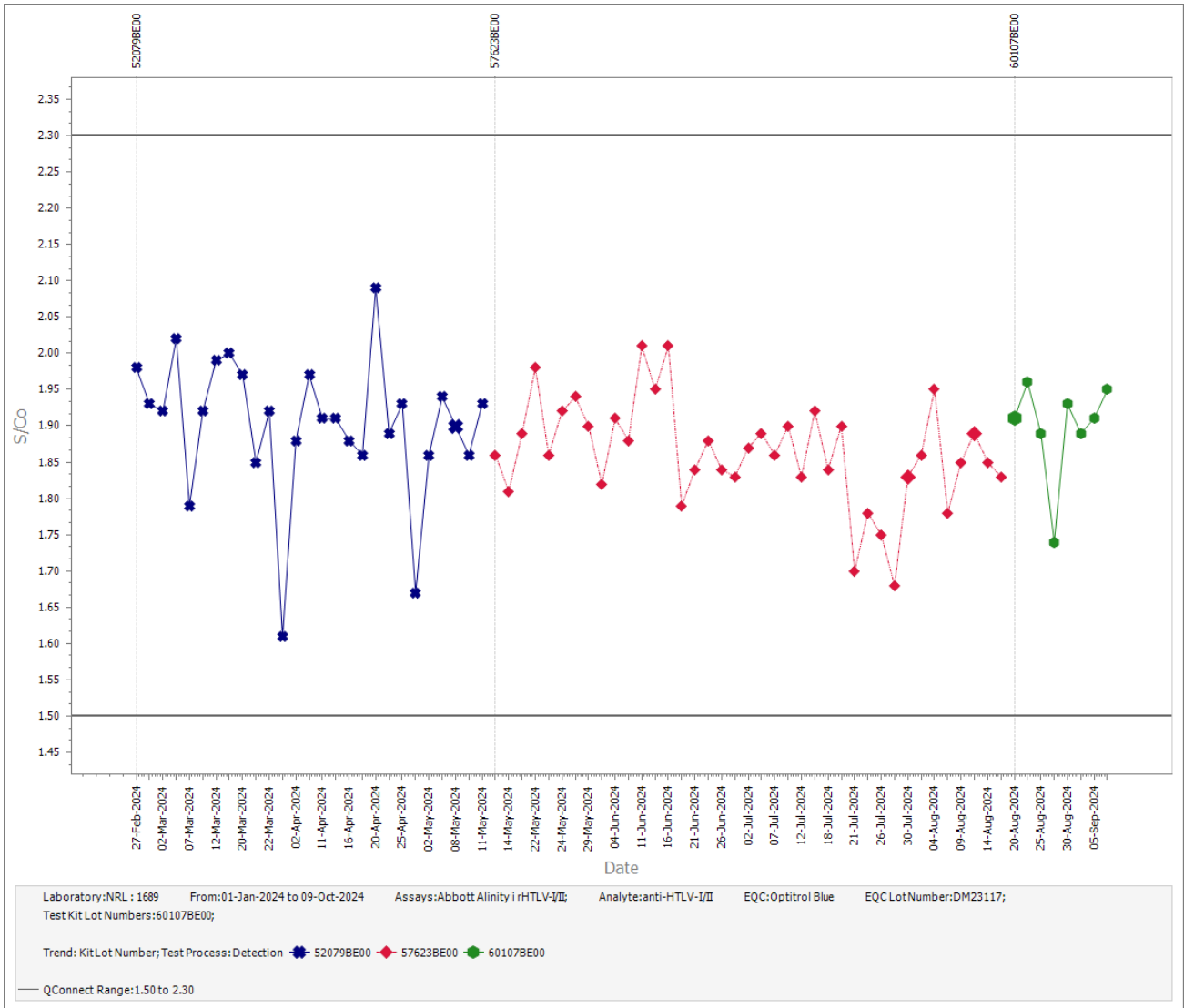


Figure 22 – Participant 1689 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

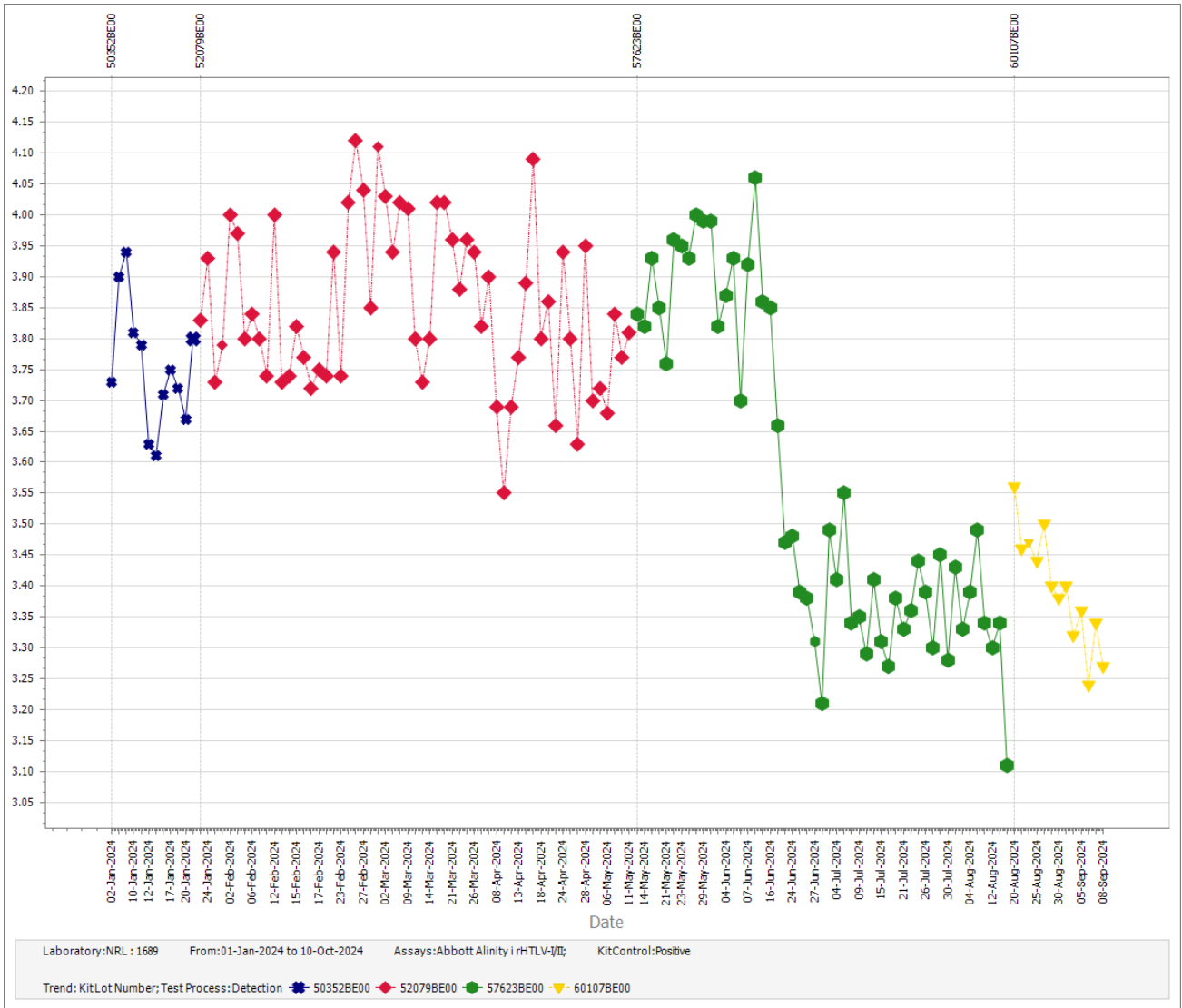


Figure 23 – Participant 1689 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

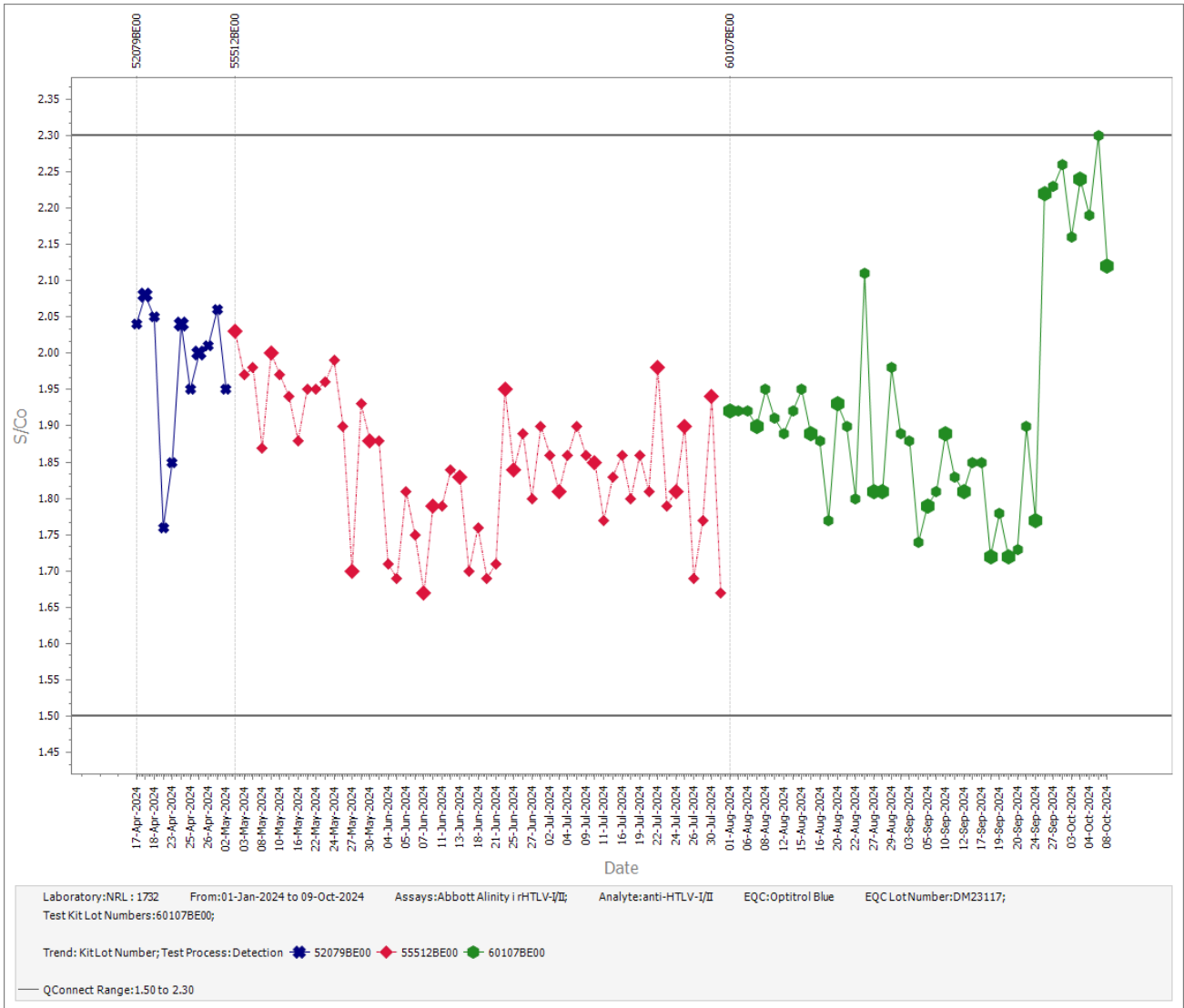


Figure 24 – Participant 1732 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.



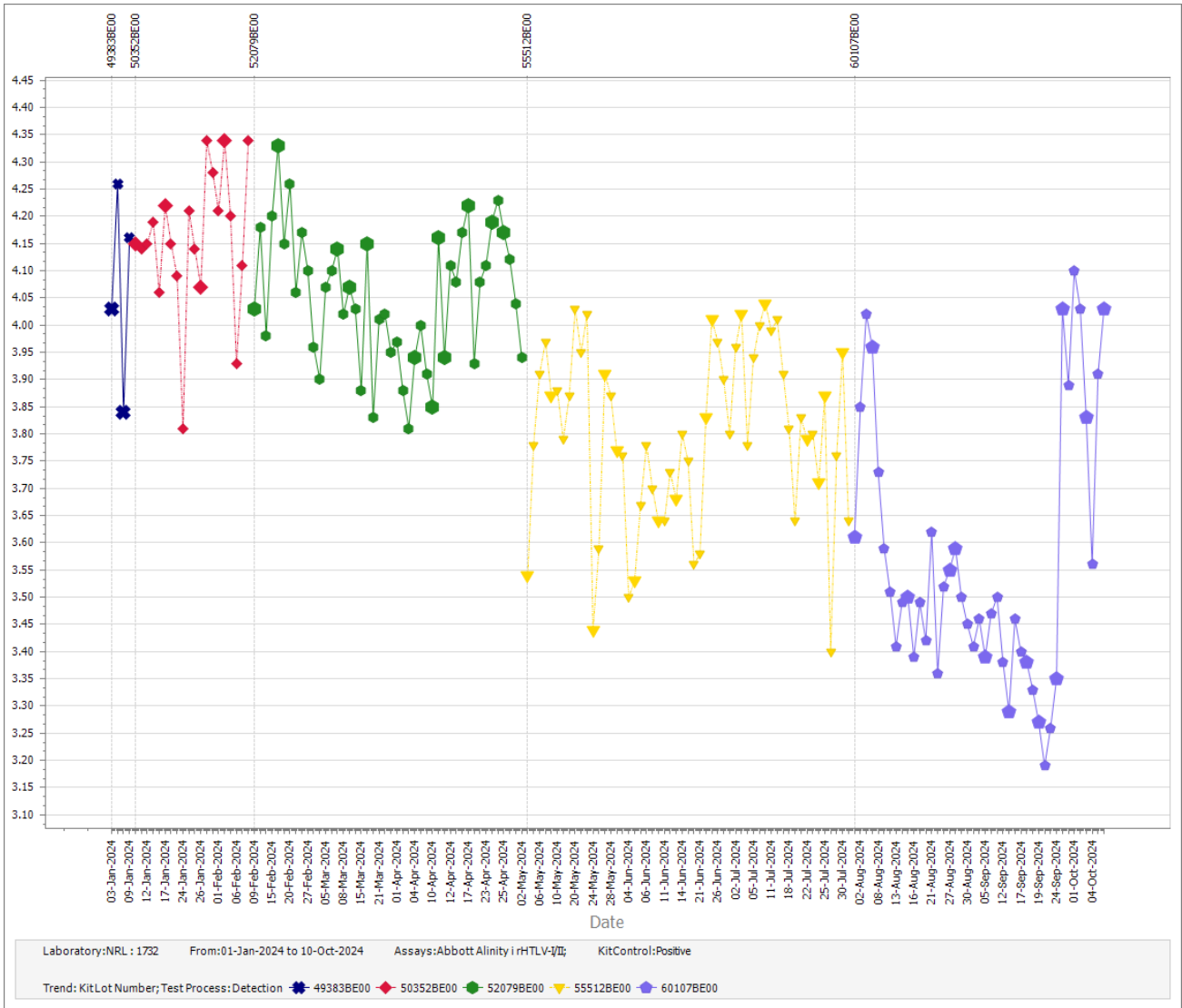


Figure 25 – Participant 1732 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

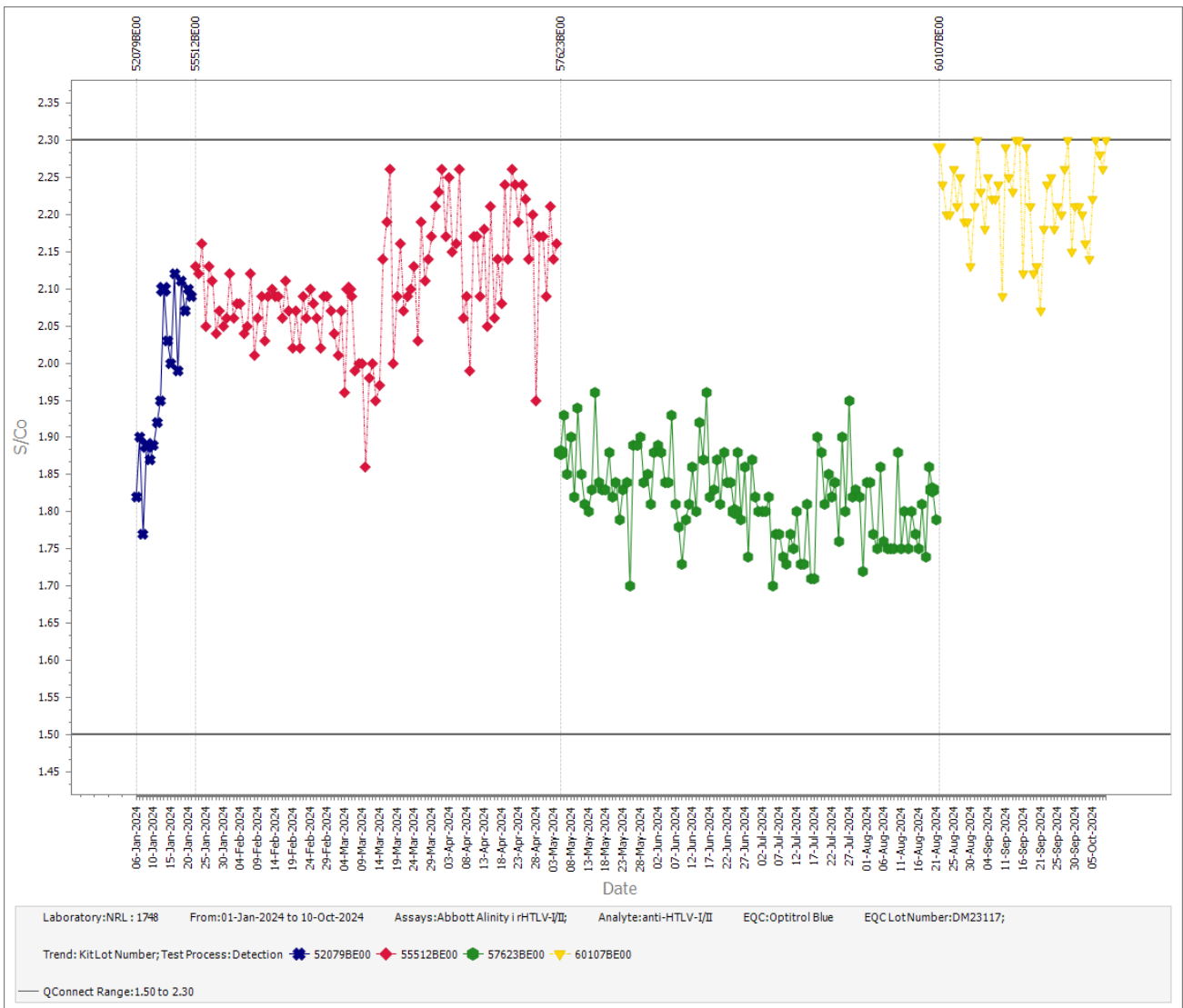


Figure 26 – Participant 1748 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

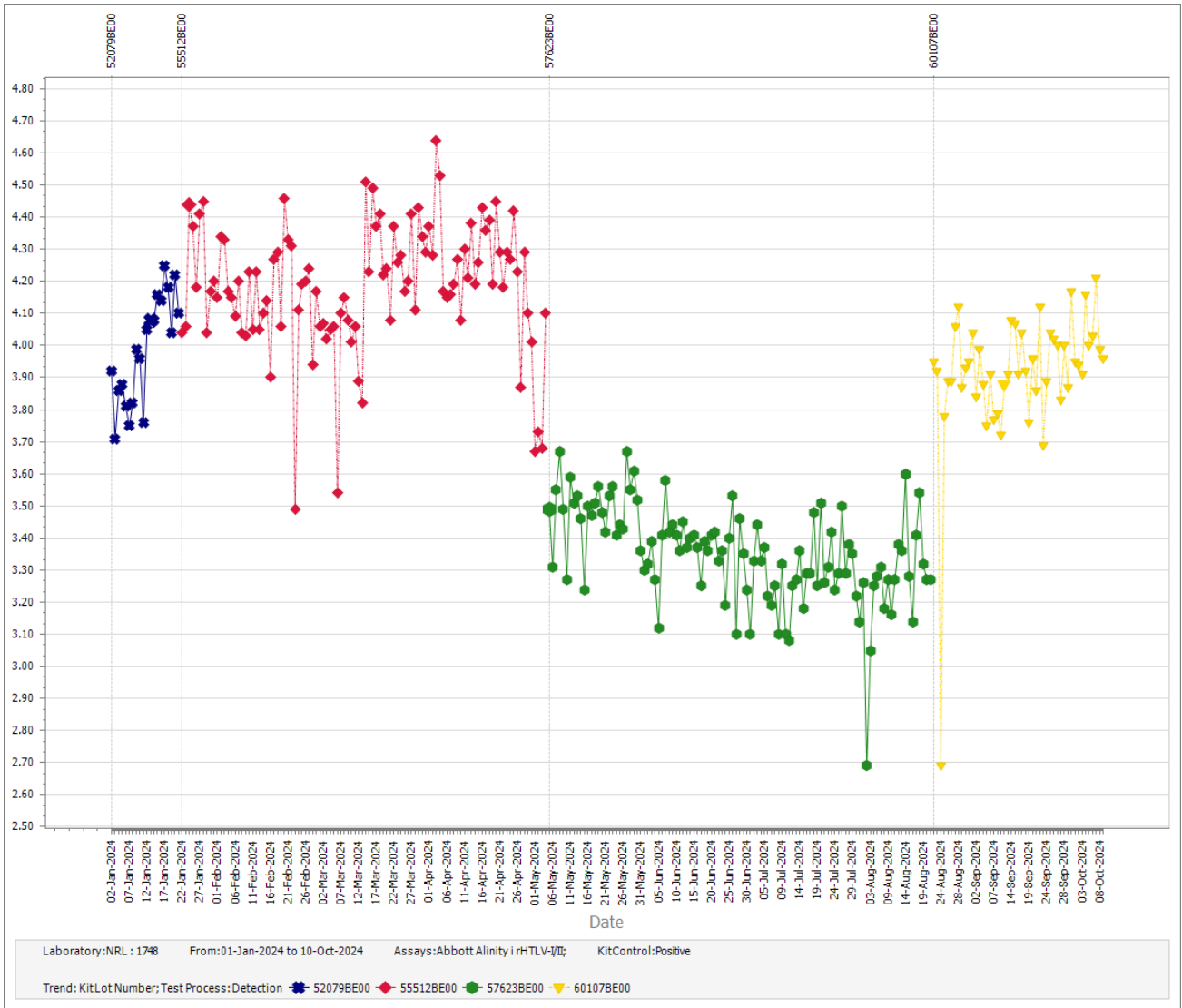


Figure 27 – Participant 1748 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

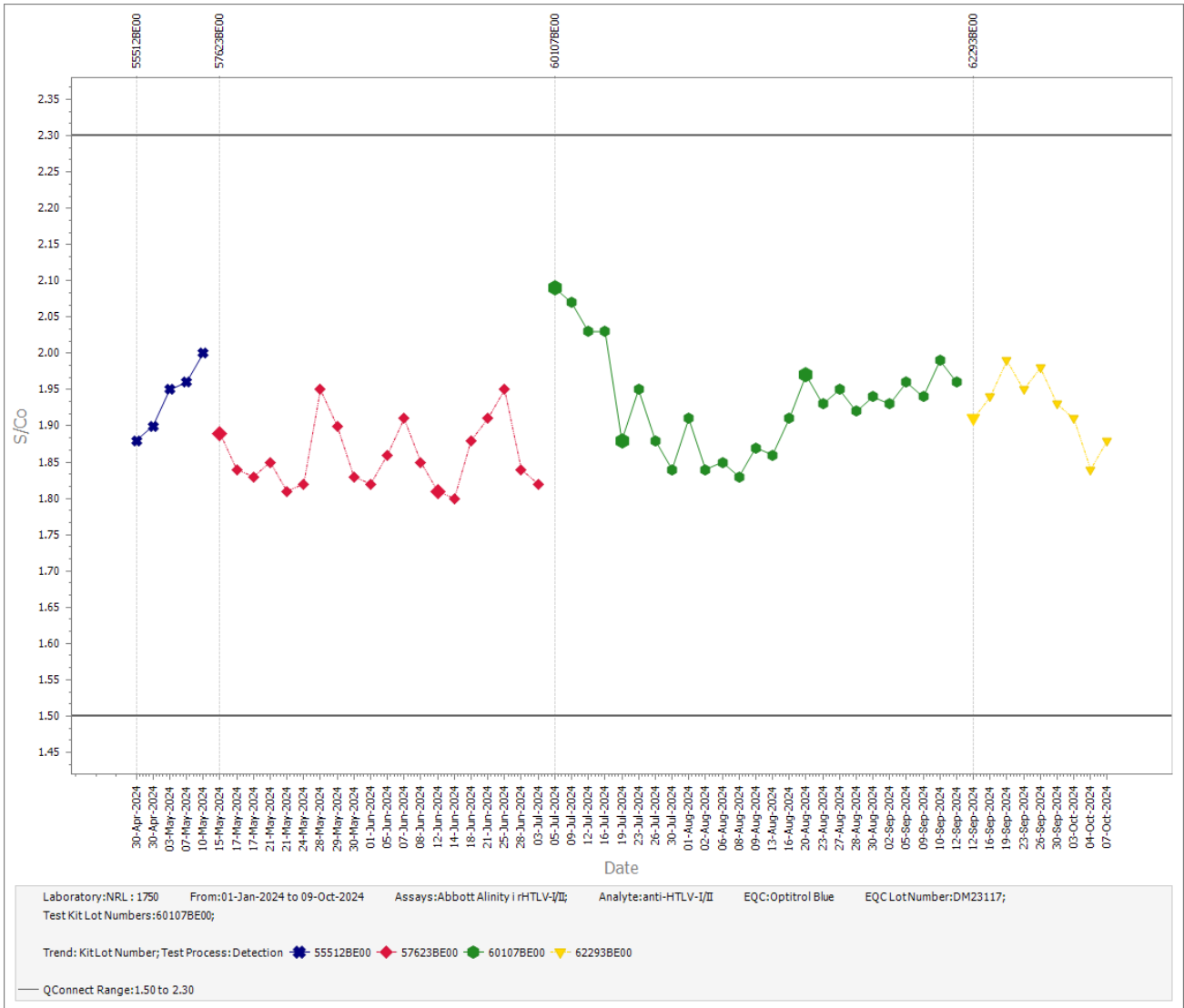


Figure 28 – Participant 1750 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

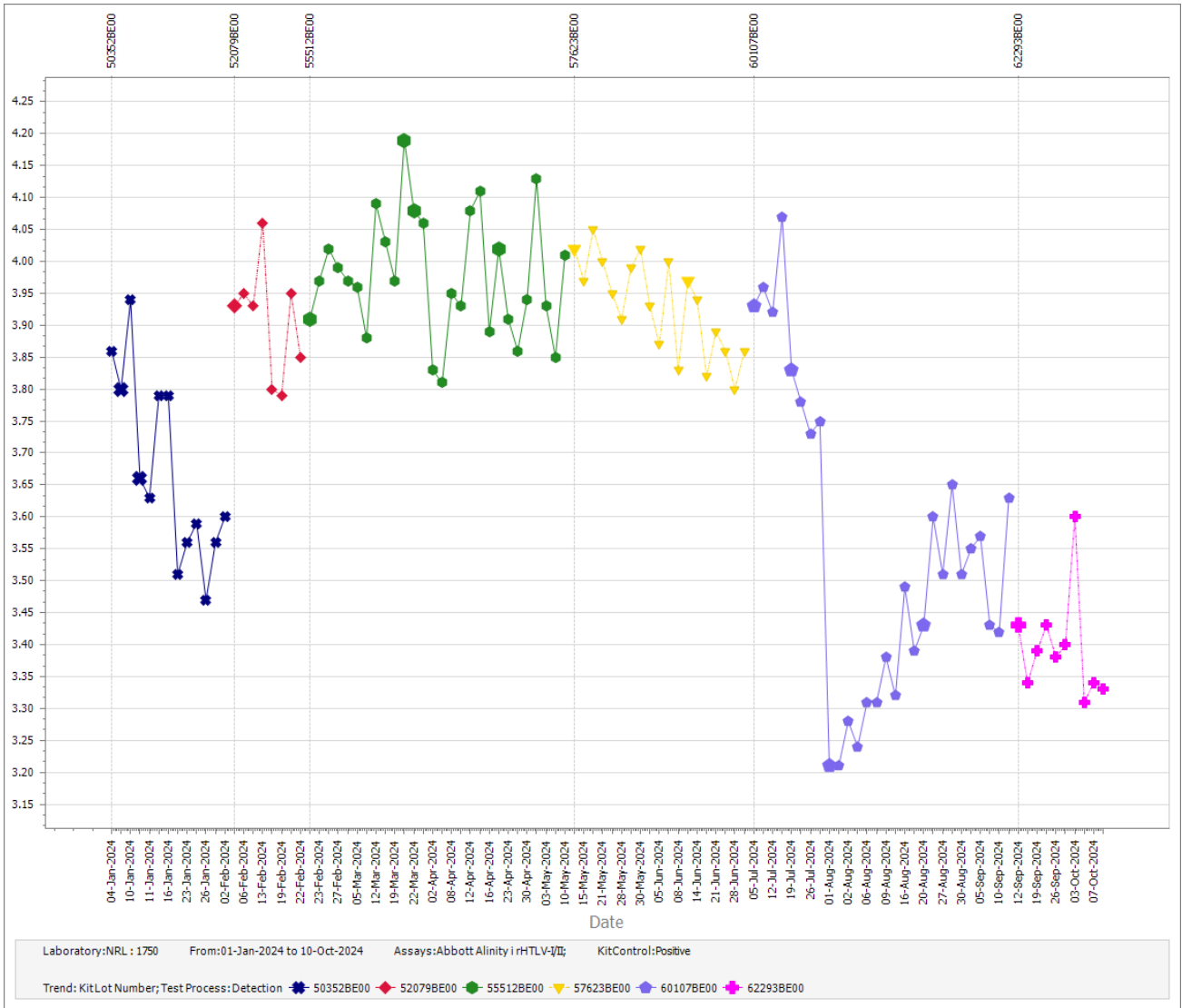


Figure 29 – Participant 1750 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

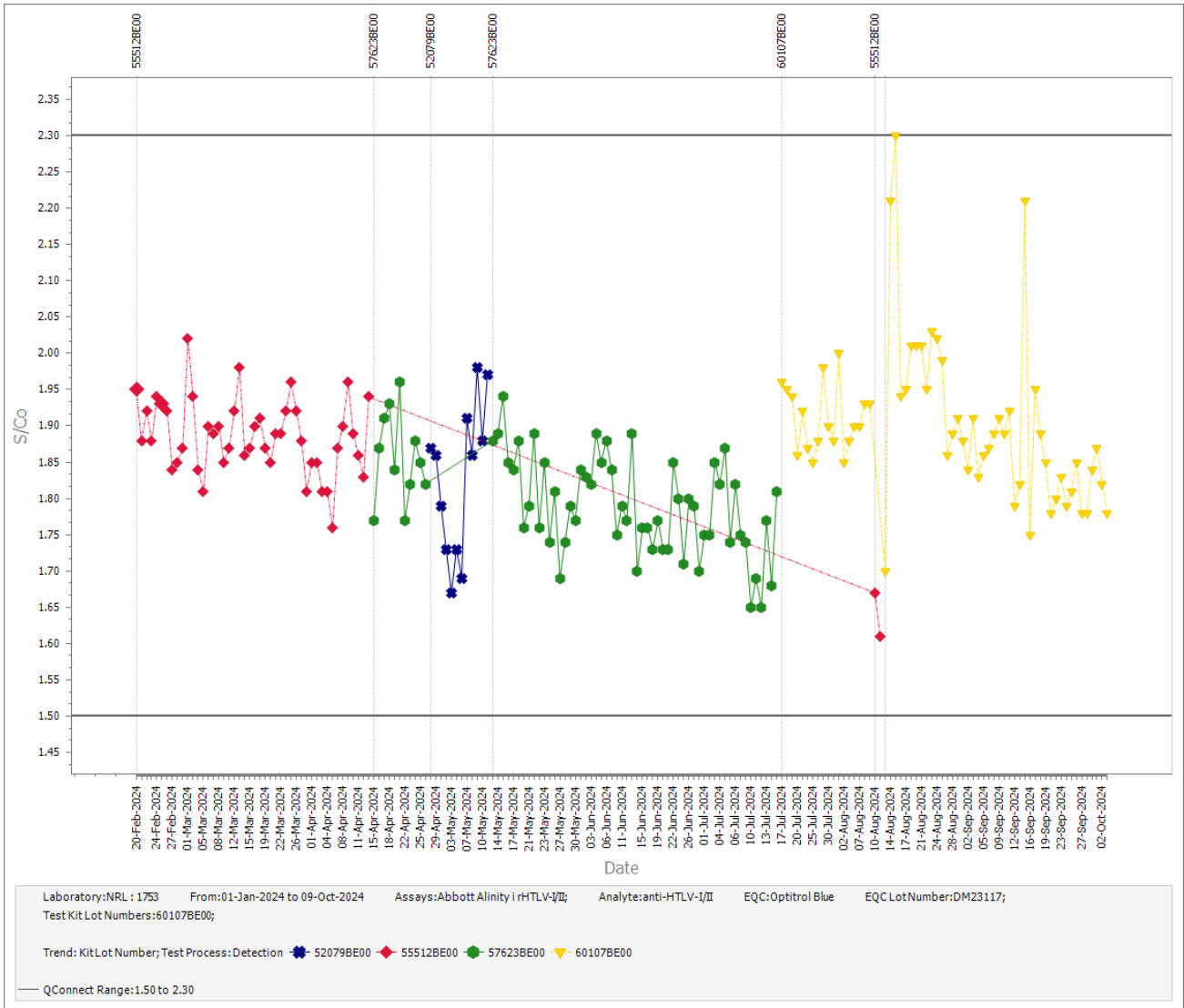


Figure 30 – Participant 1753 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

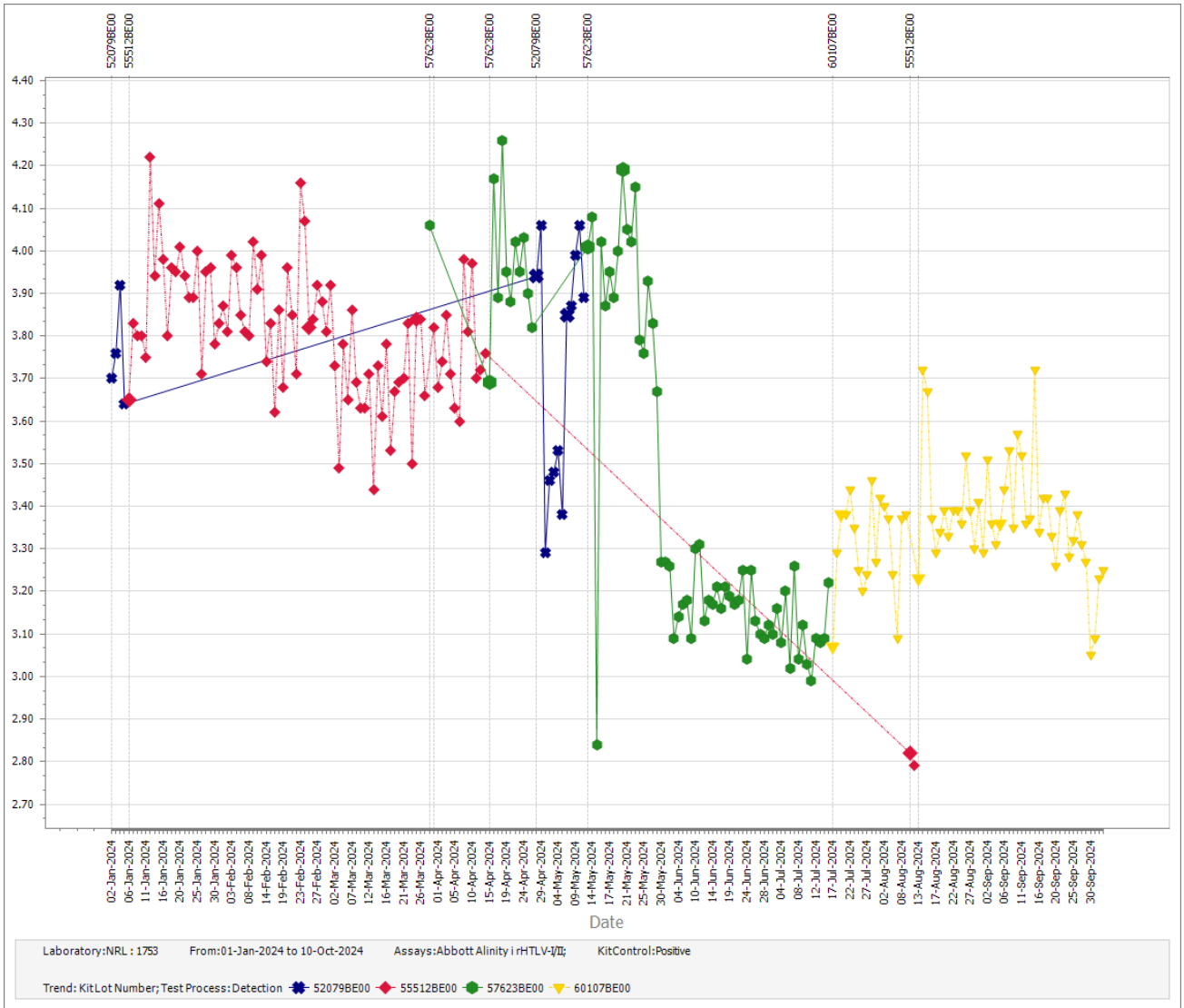


Figure 31 – Participant 1753 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

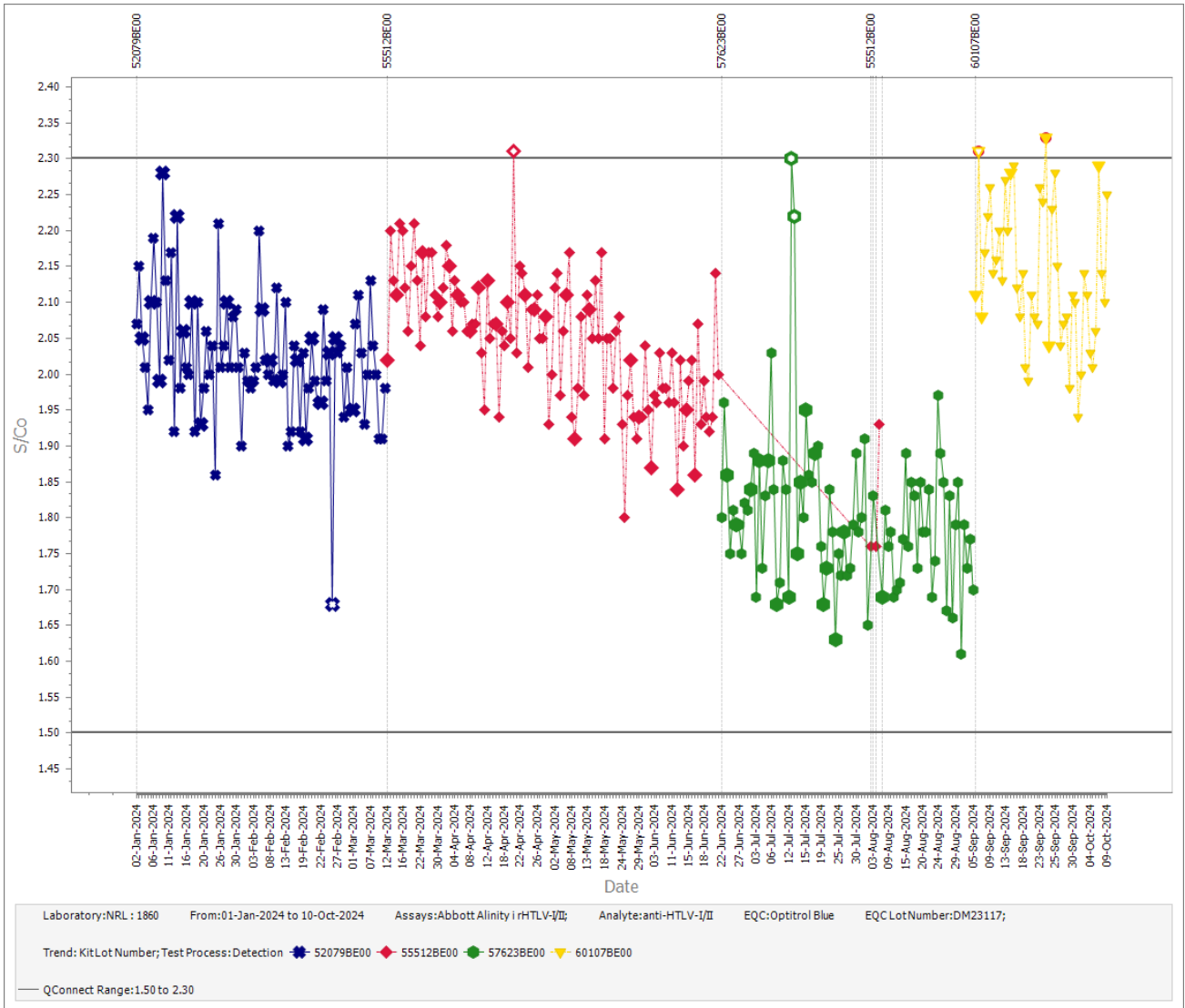


Figure 32 – Participant 1860 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.



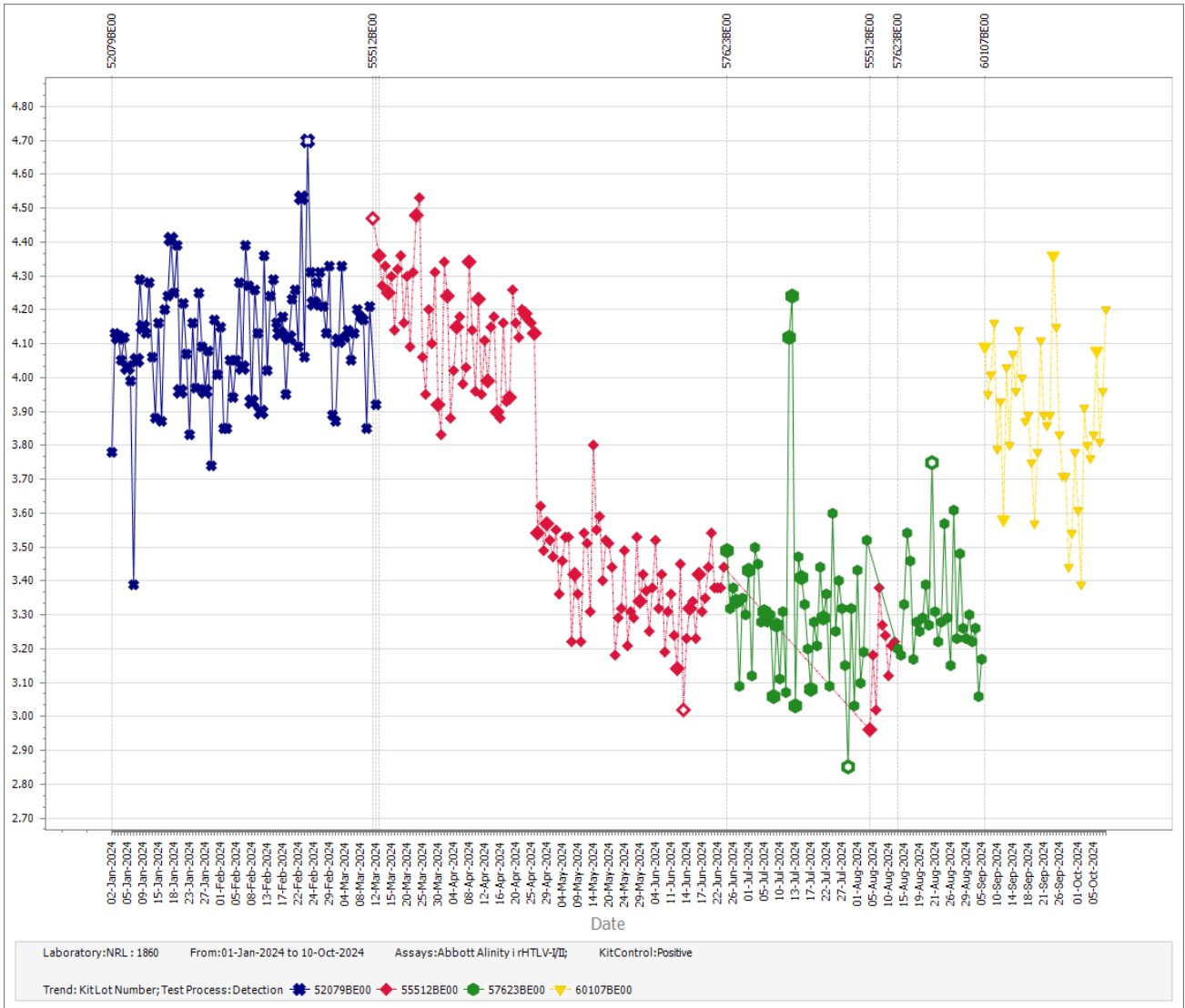


Figure 33 – Participant 1860 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

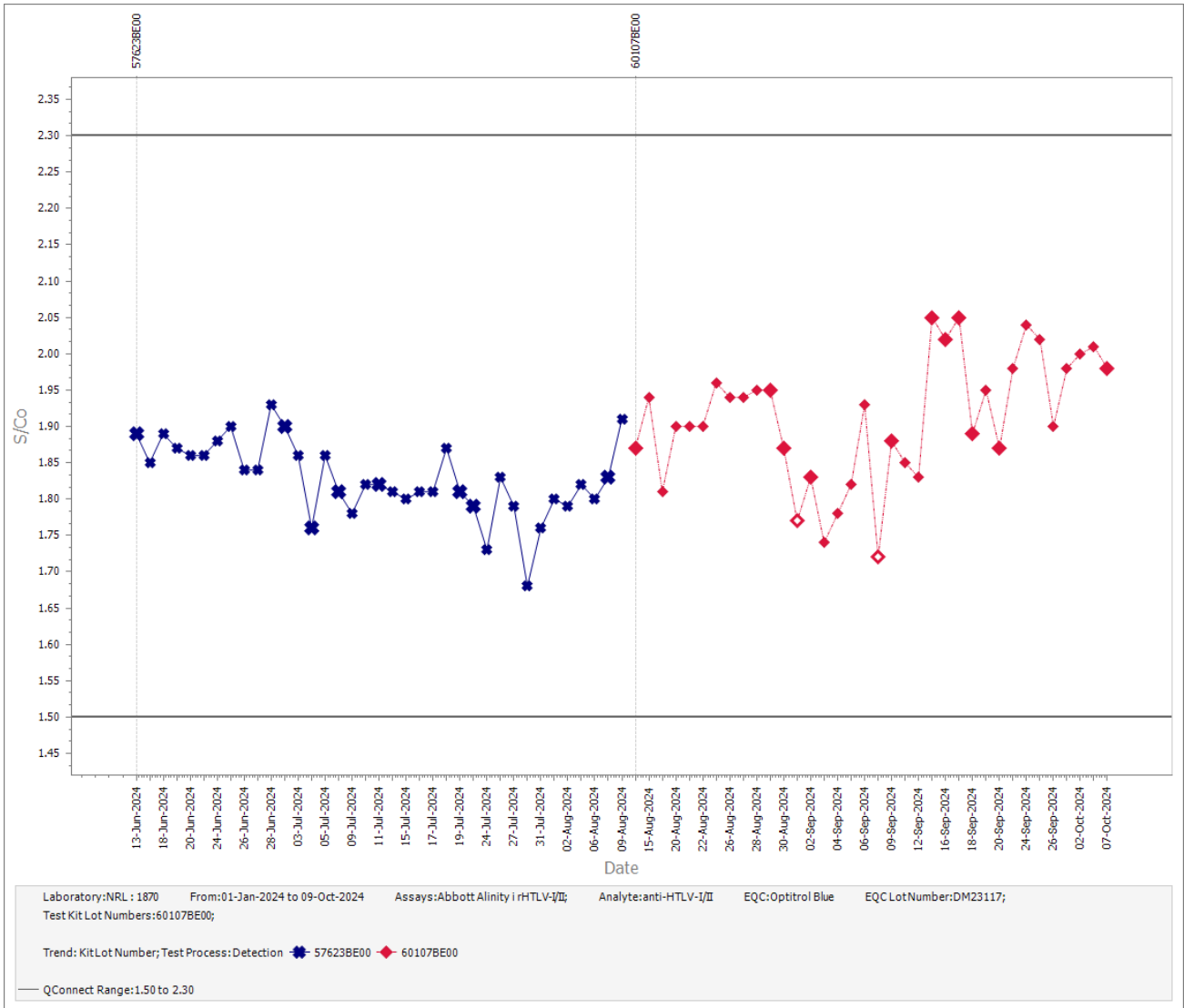


Figure 34 – Participant 1870 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

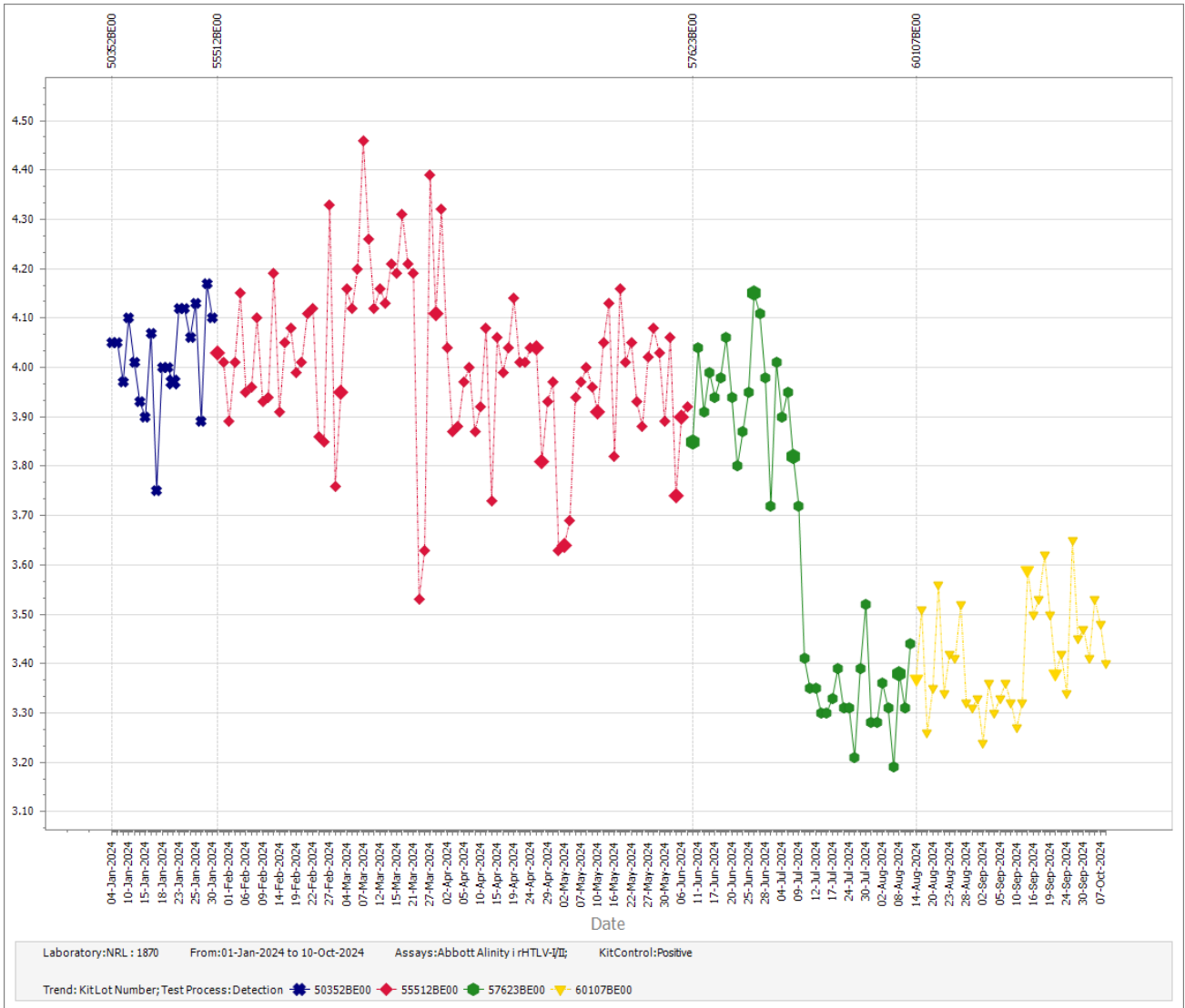


Figure 35 – Participant 1870 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

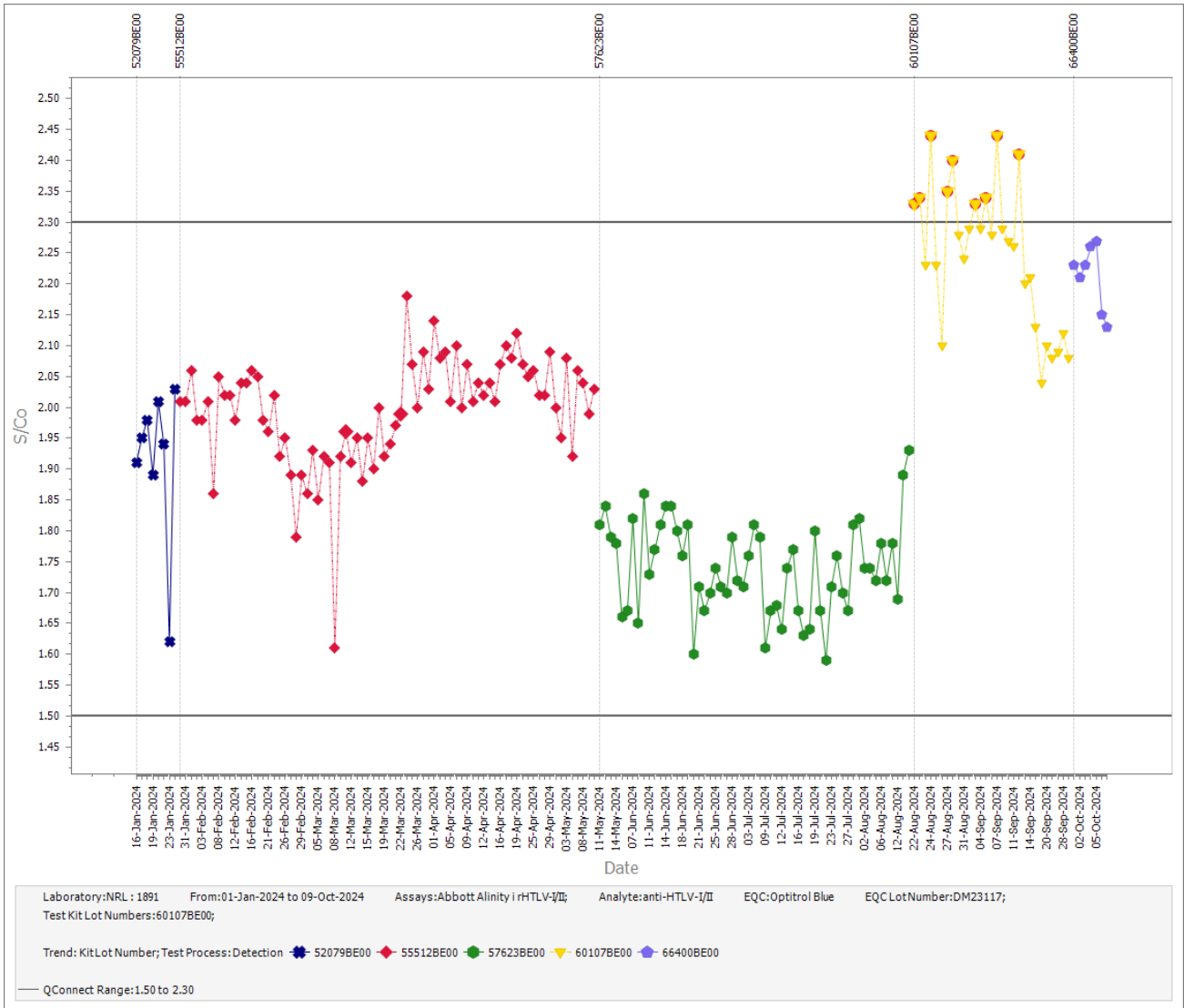


Figure 36 – Participant 1891 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

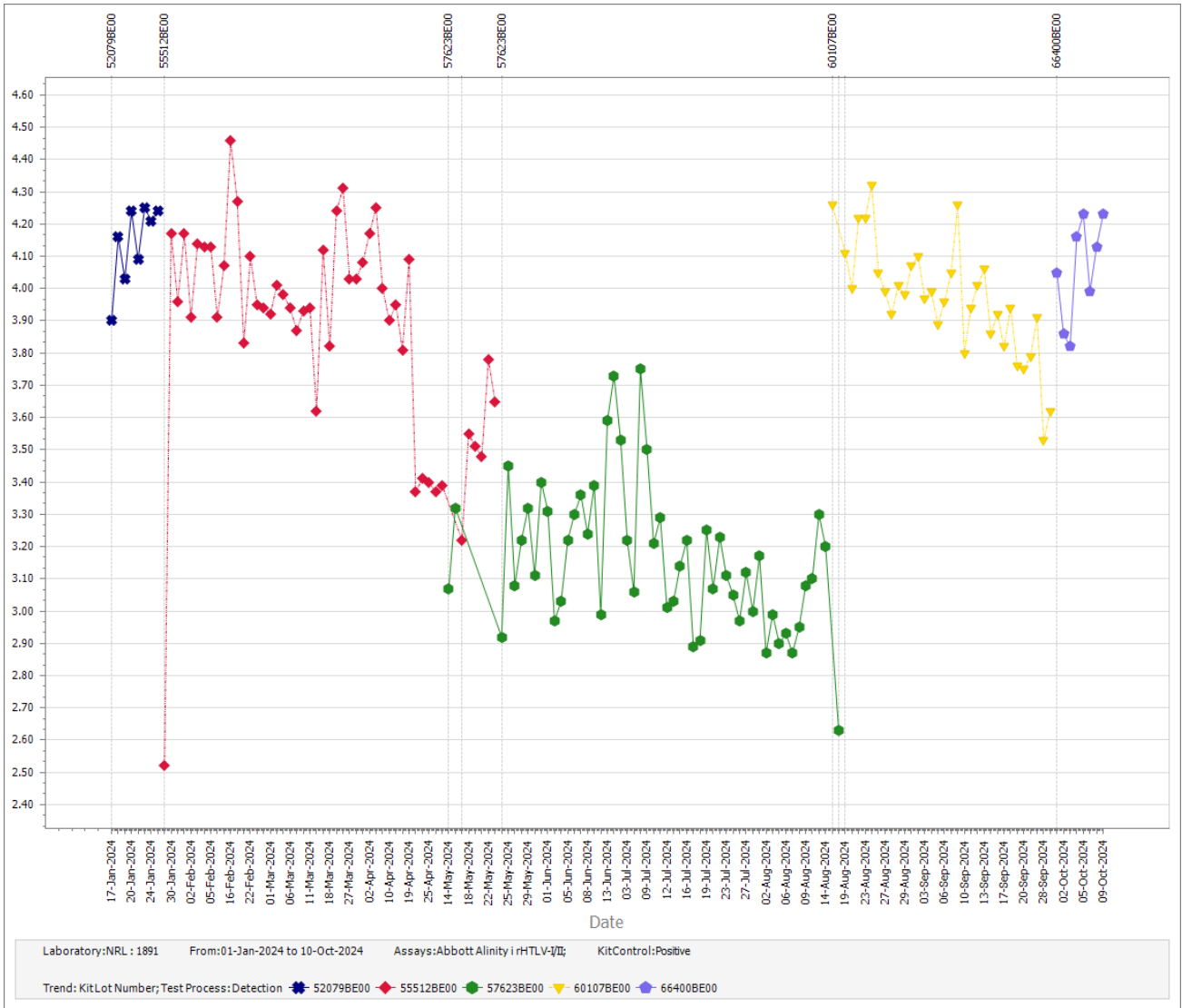


Figure 37 – Participant 1891 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

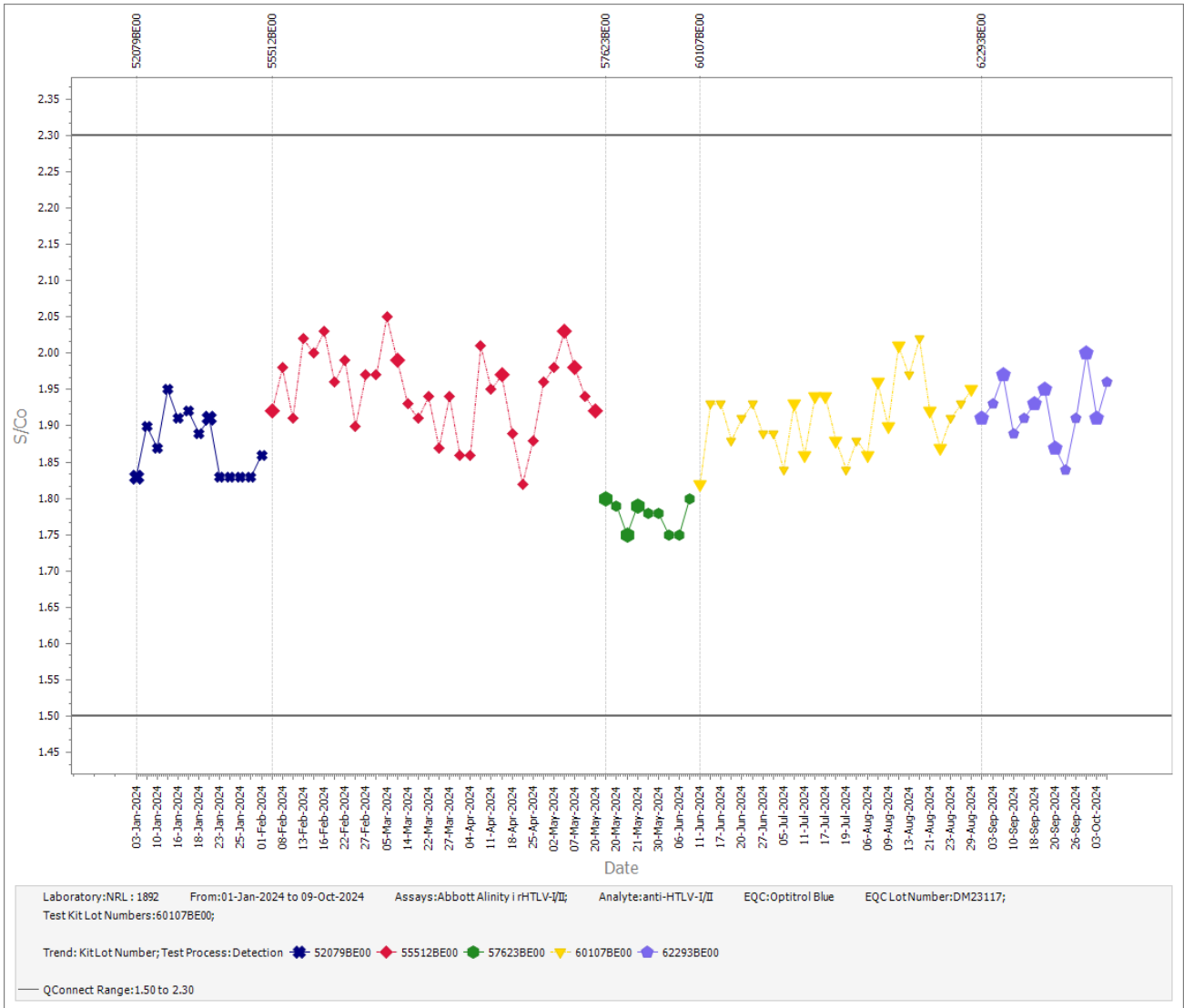


Figure 38 – Participant 1892 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

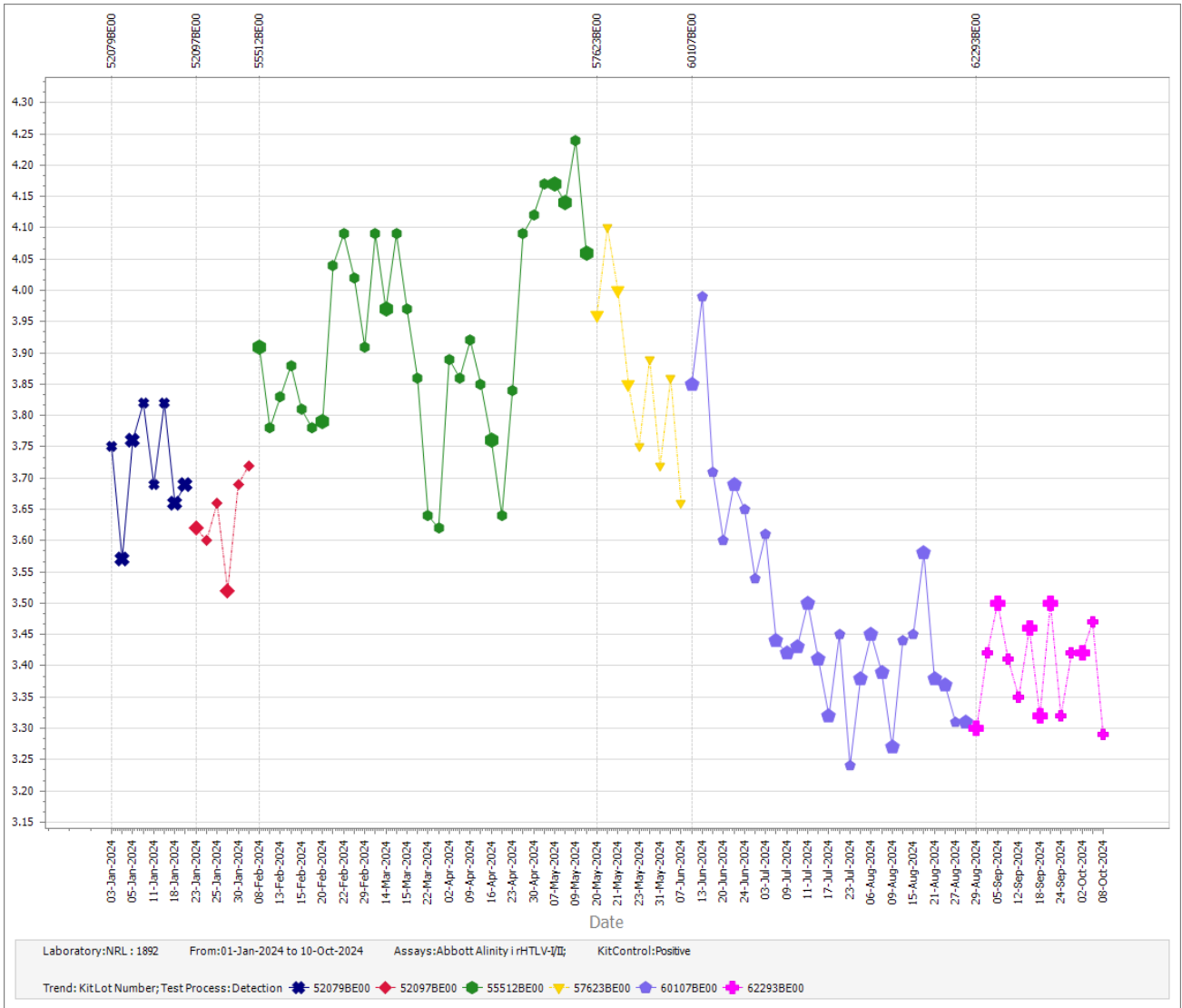


Figure 39 – Participant 1892 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

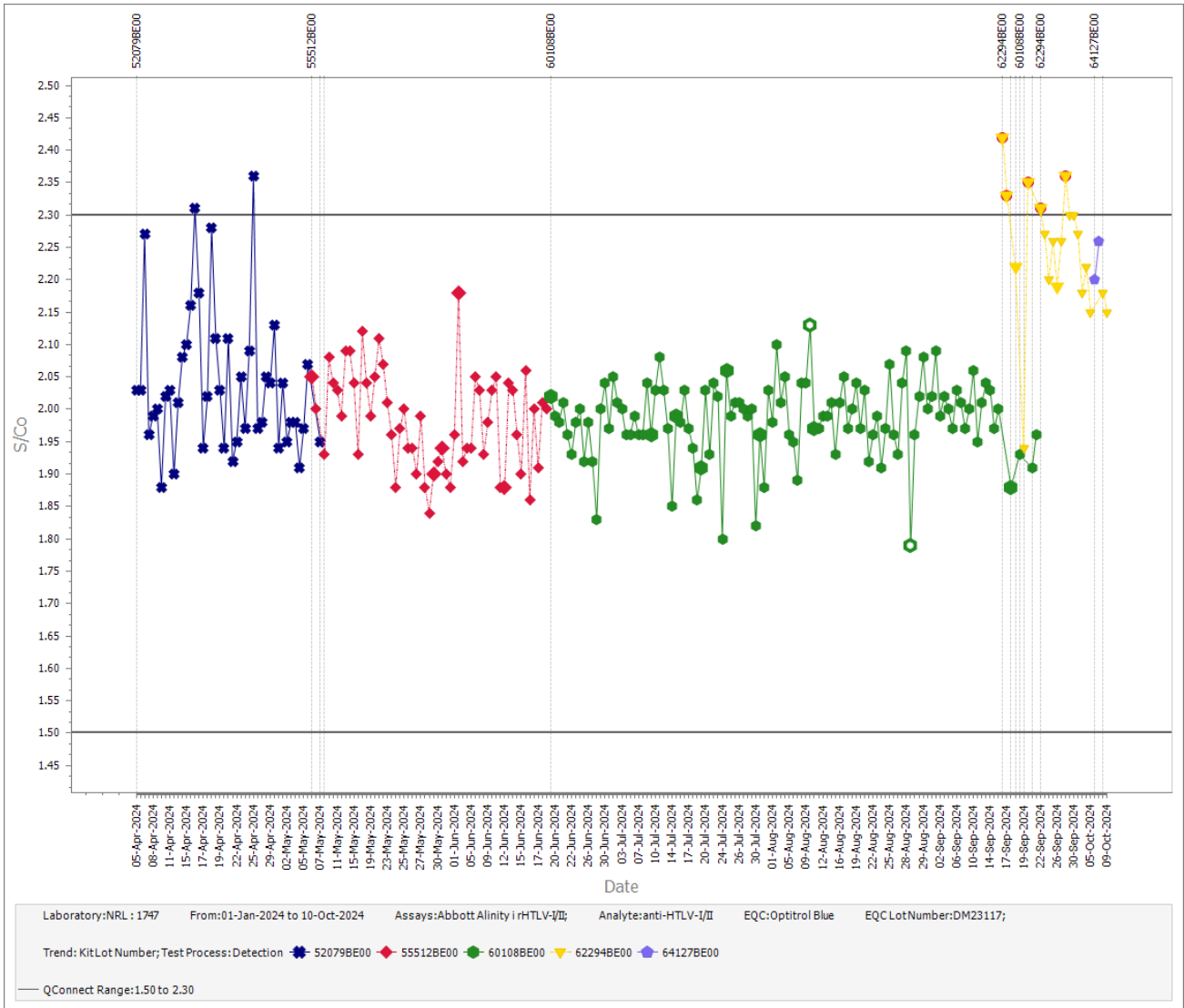


Figure 40 – Participant 1747 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.



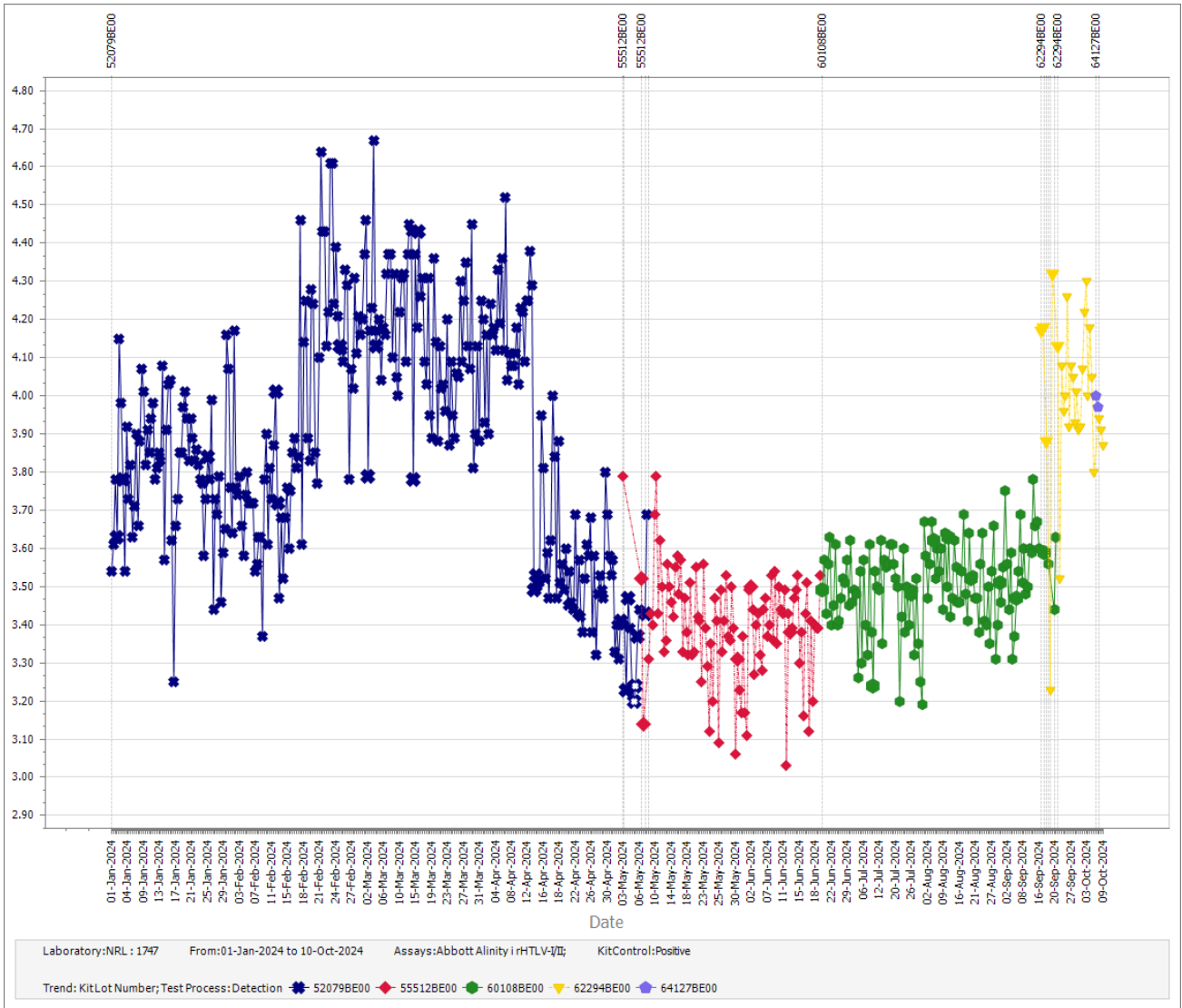


Figure 41 – Participant 1747 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

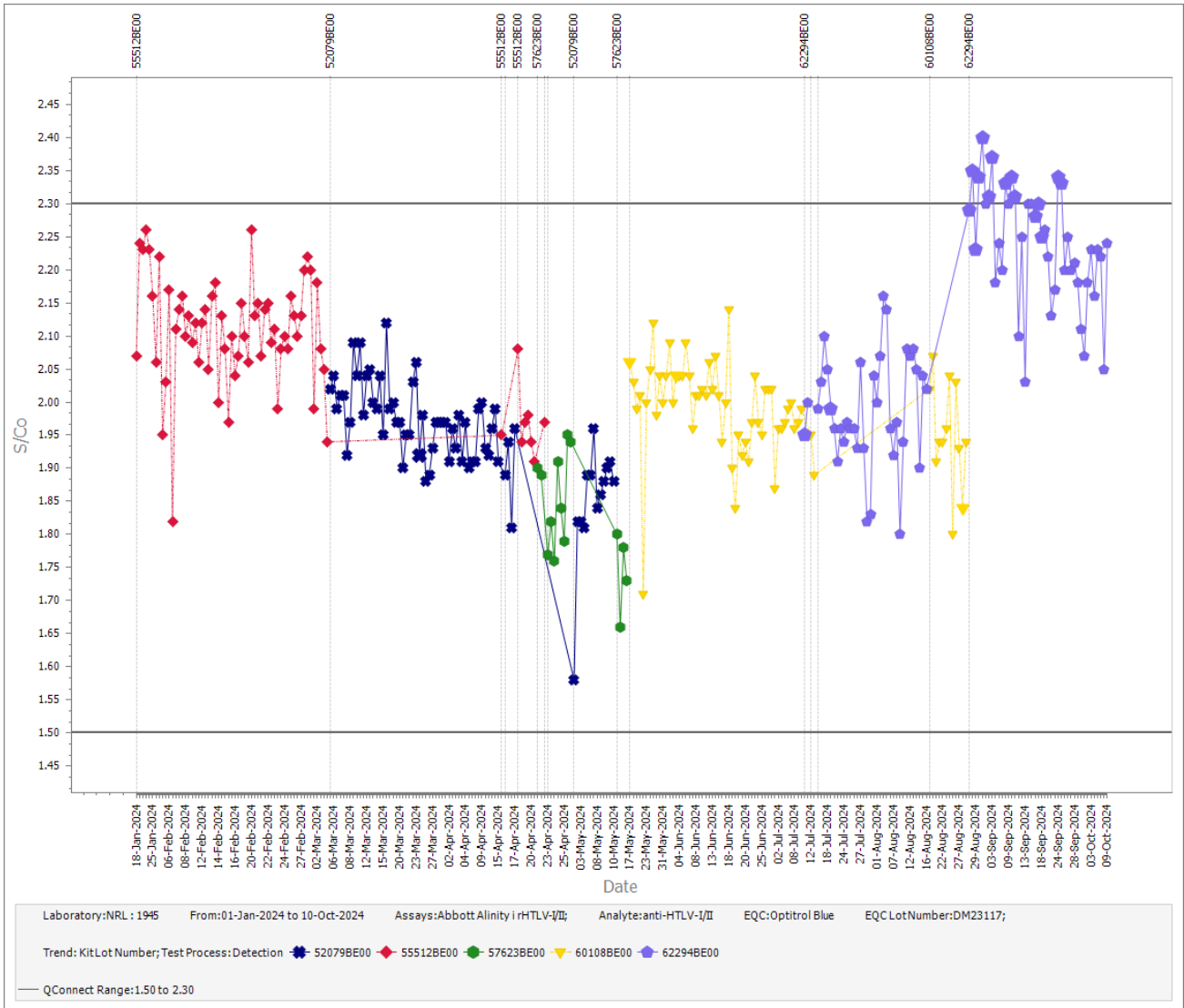


Figure 42 – Participant 1945 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

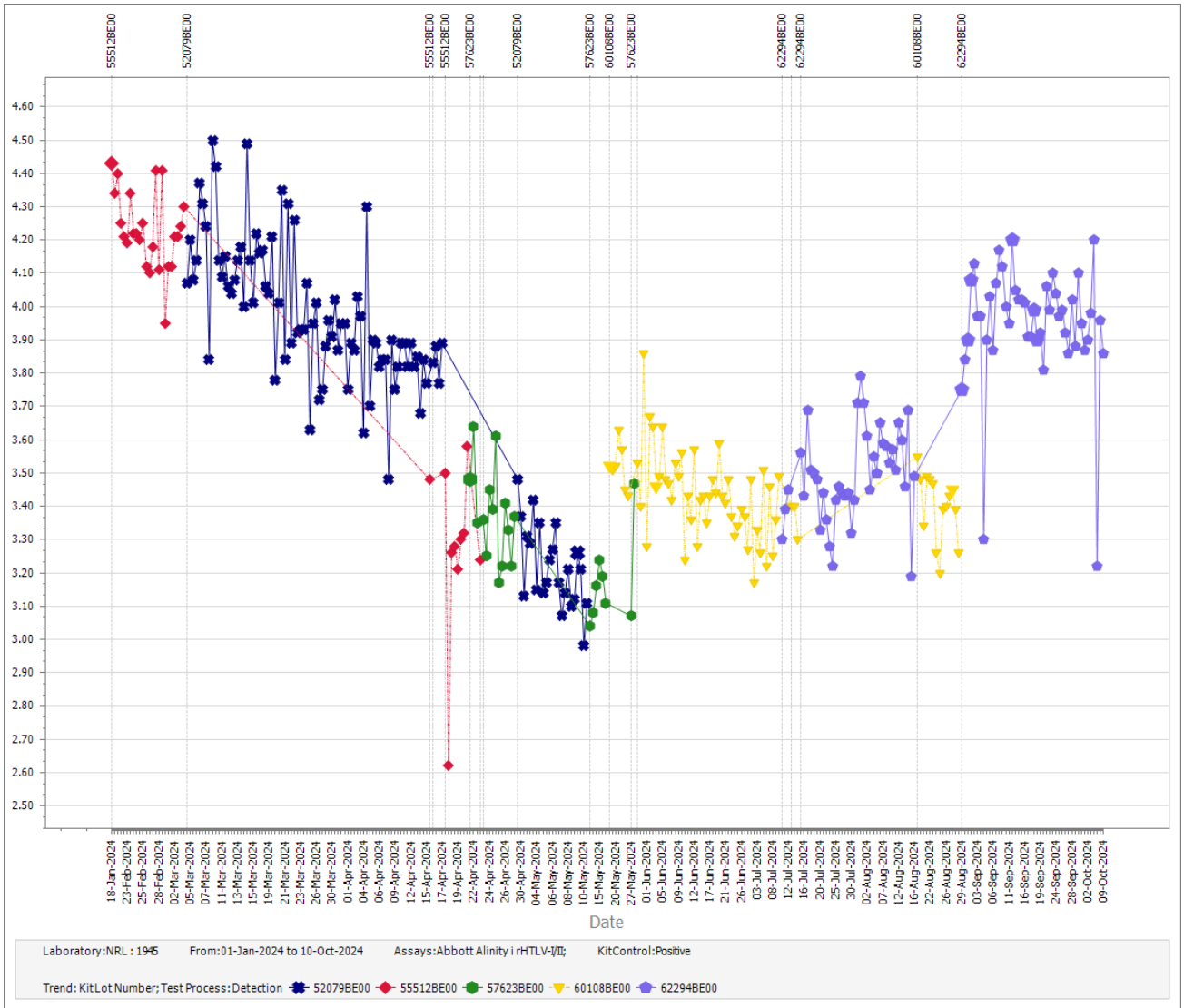
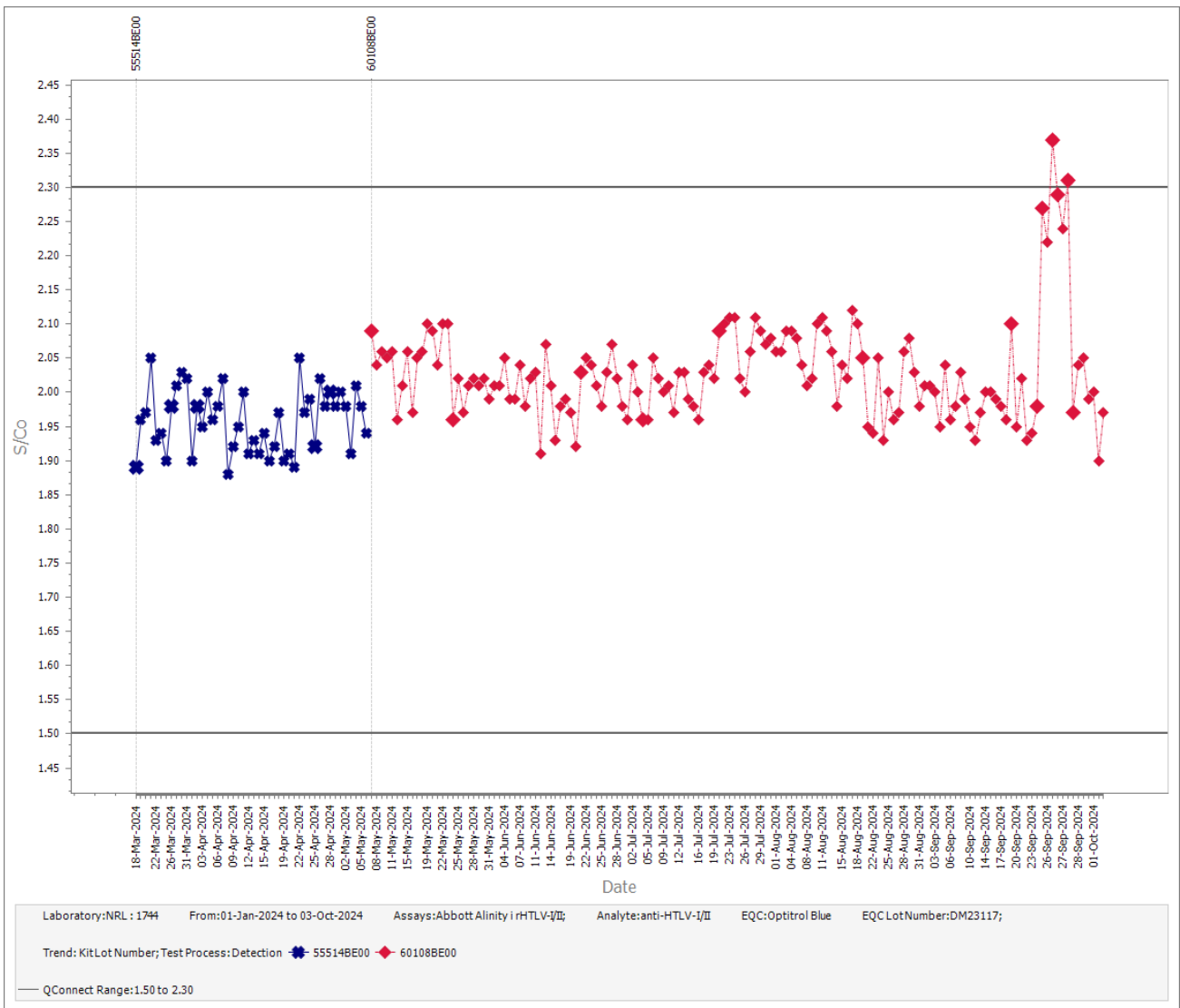


Figure 43 – Participant 1945 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.



• Figure 44 – Participant 1744 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

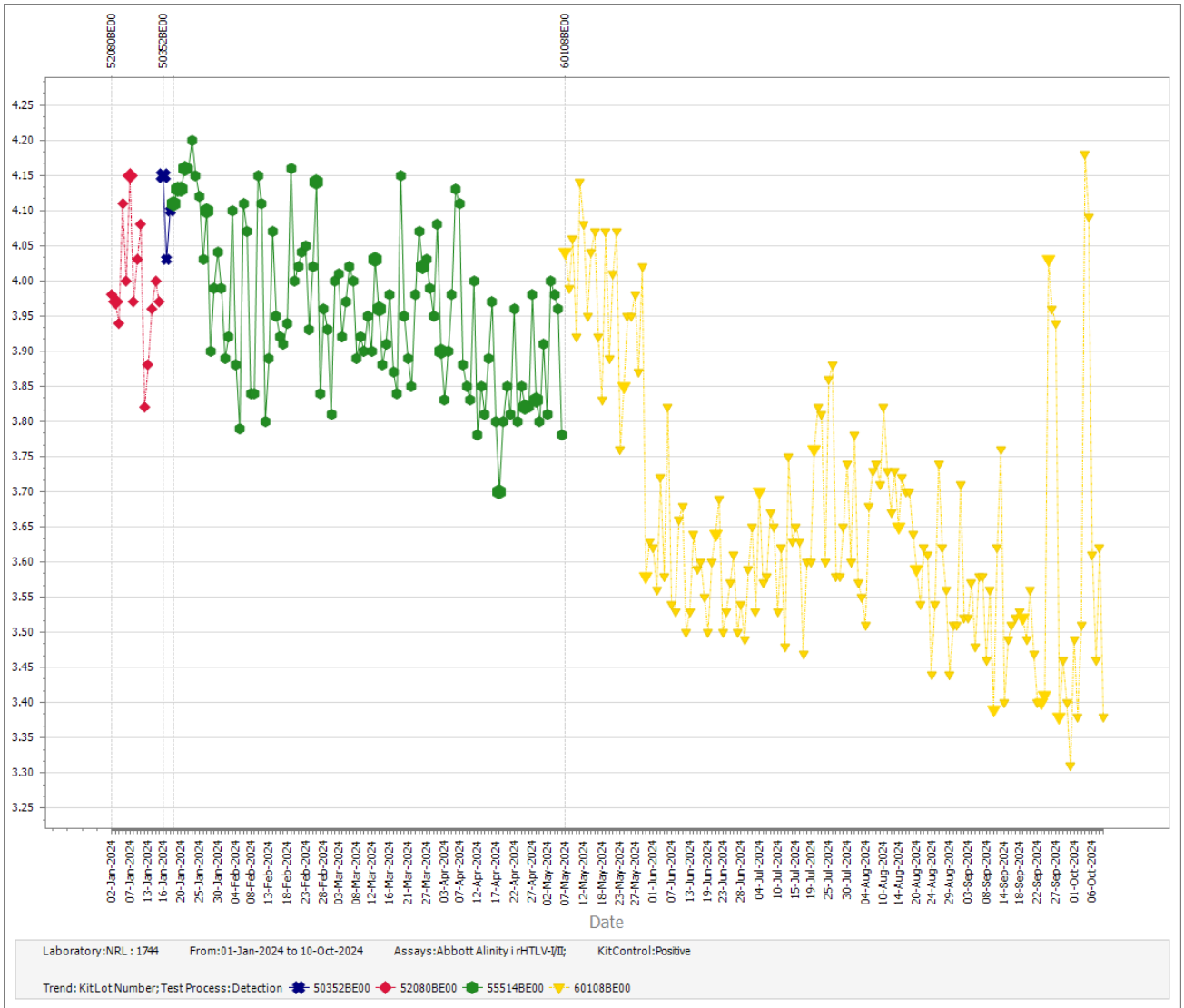


Figure 45 – Participant 1744 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

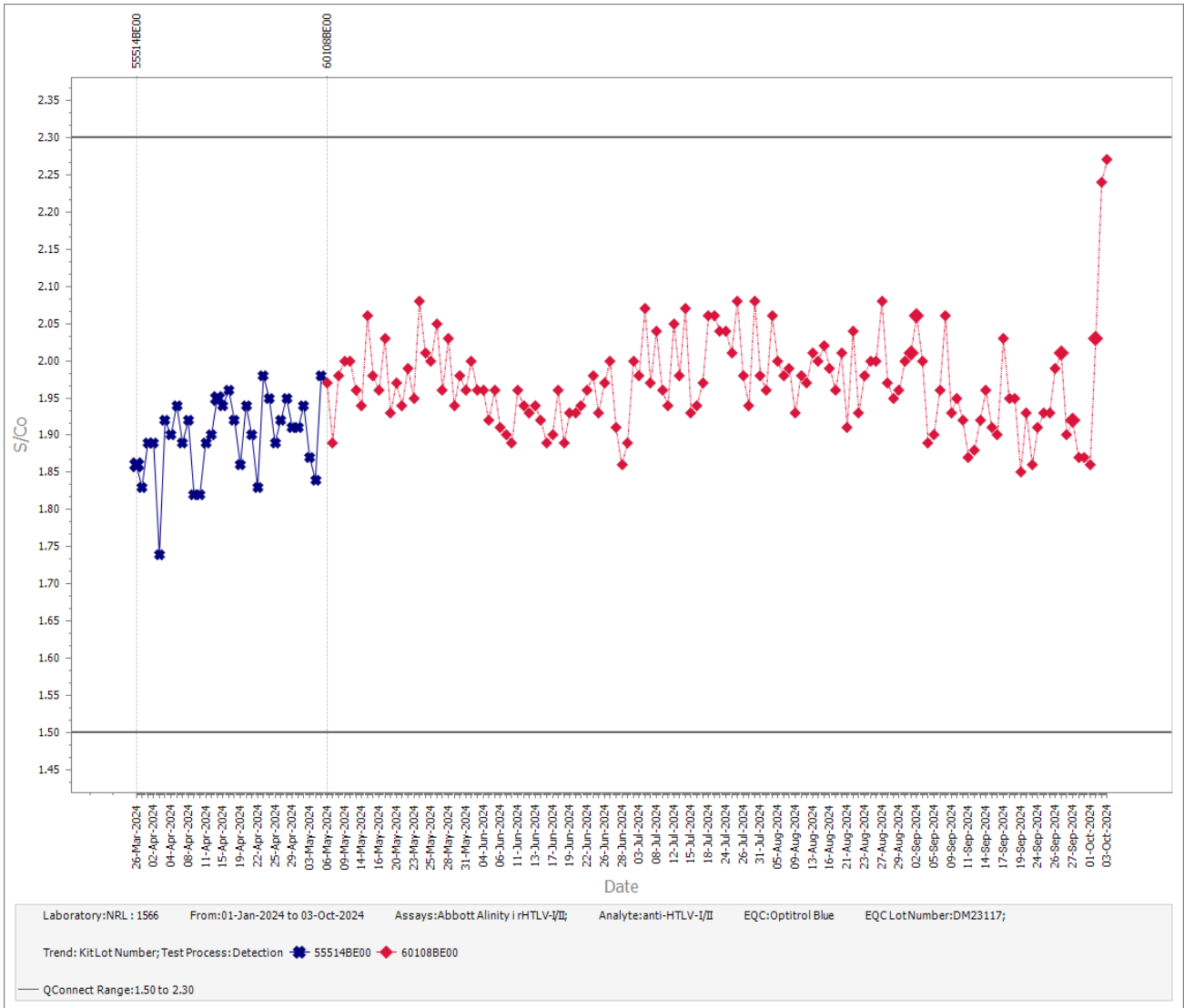


Figure 46 – Participant 1566 Levy Jennings chart grouped by reagent lot illustrating data reported for Optitrol Blue DM23117 when testing on the Abbott Alinity i rHTLV-I/II assay.

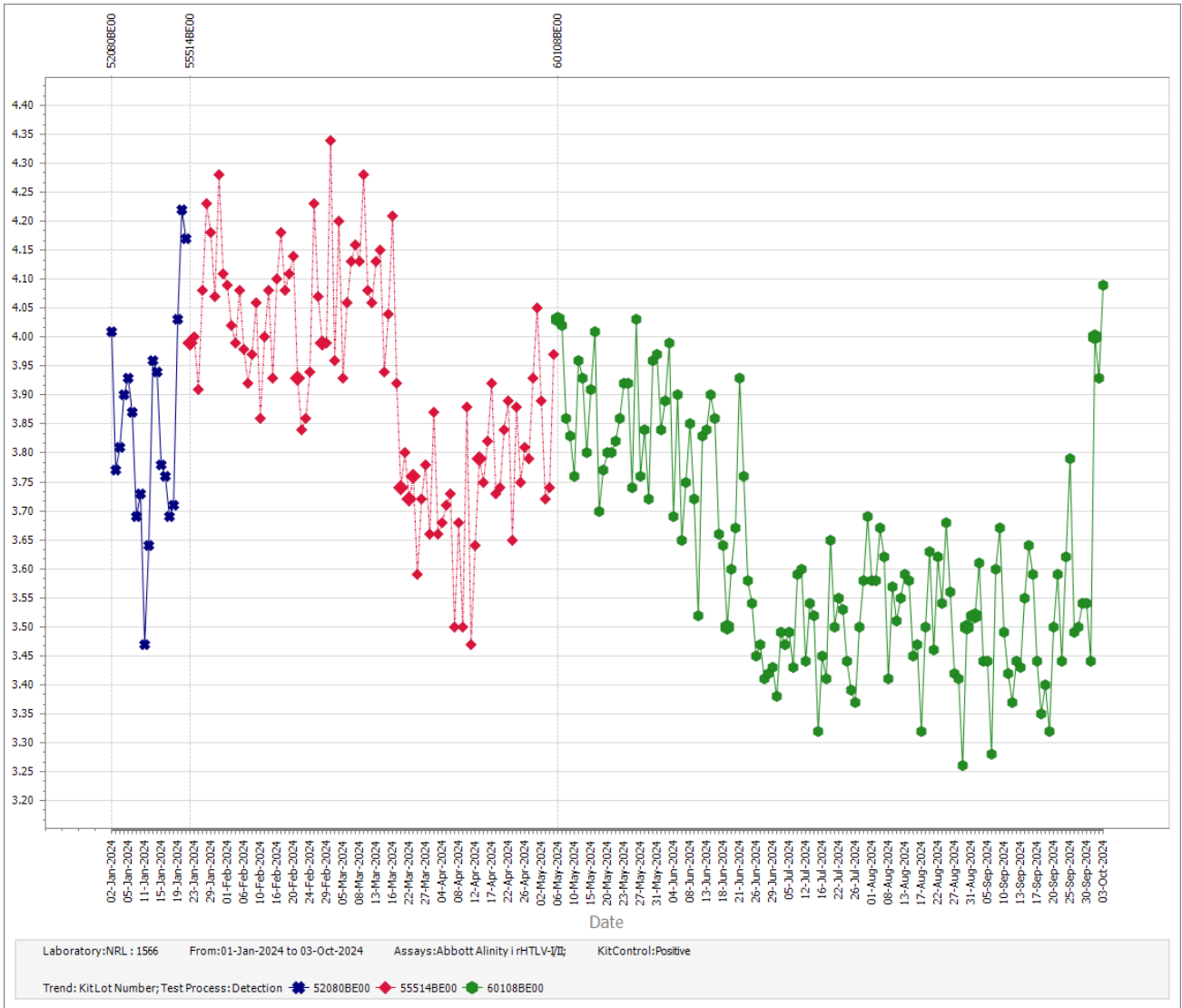


Figure 47 – Participant 1566 Levy Jennings chart grouped by reagent lot illustrating shift in data for Positive Kit Control when testing on the Abbott Alinity i rHTLV-I/II assay.

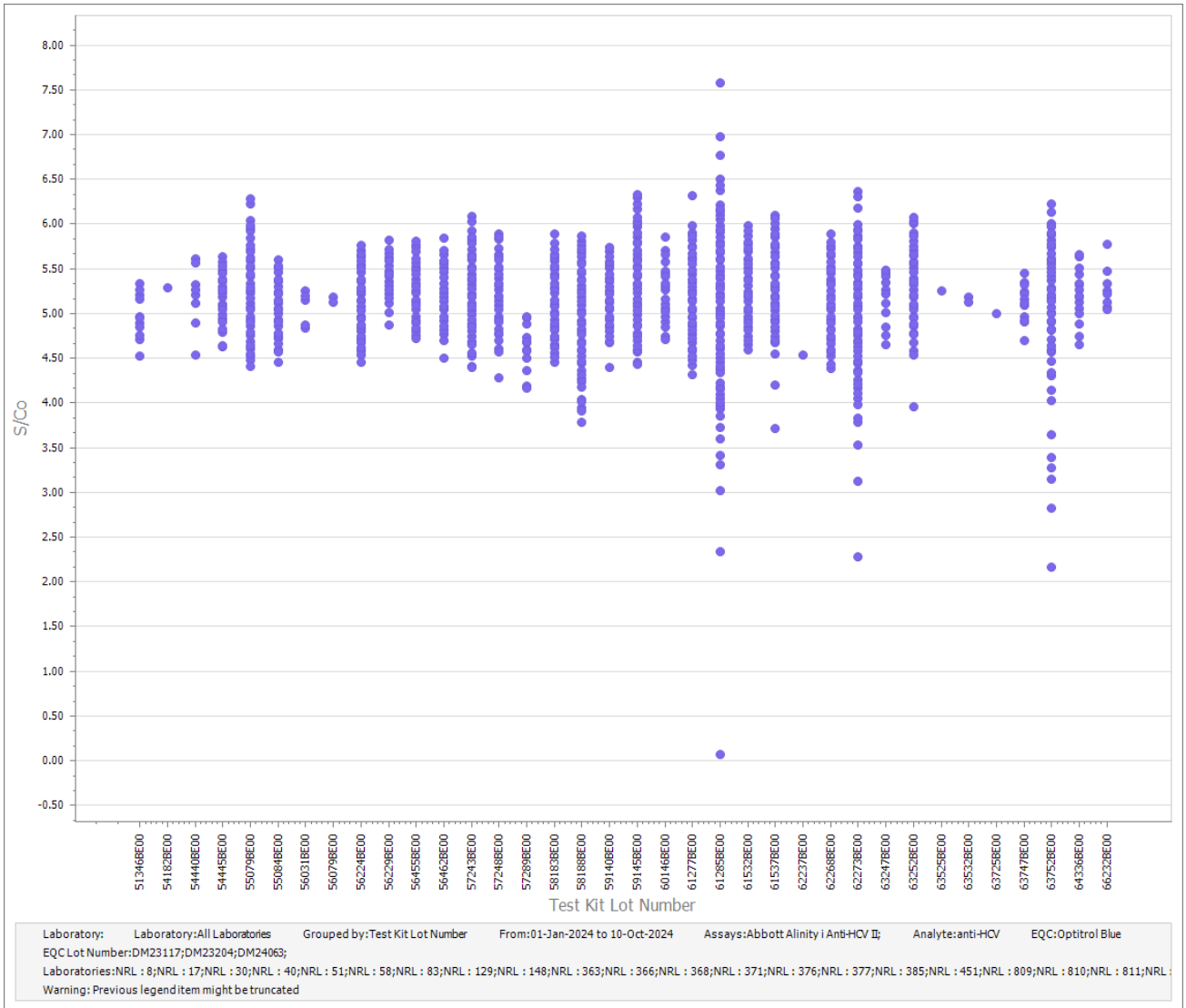


Figure 48 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Anti-HCV II assay sorted by reagent lots.



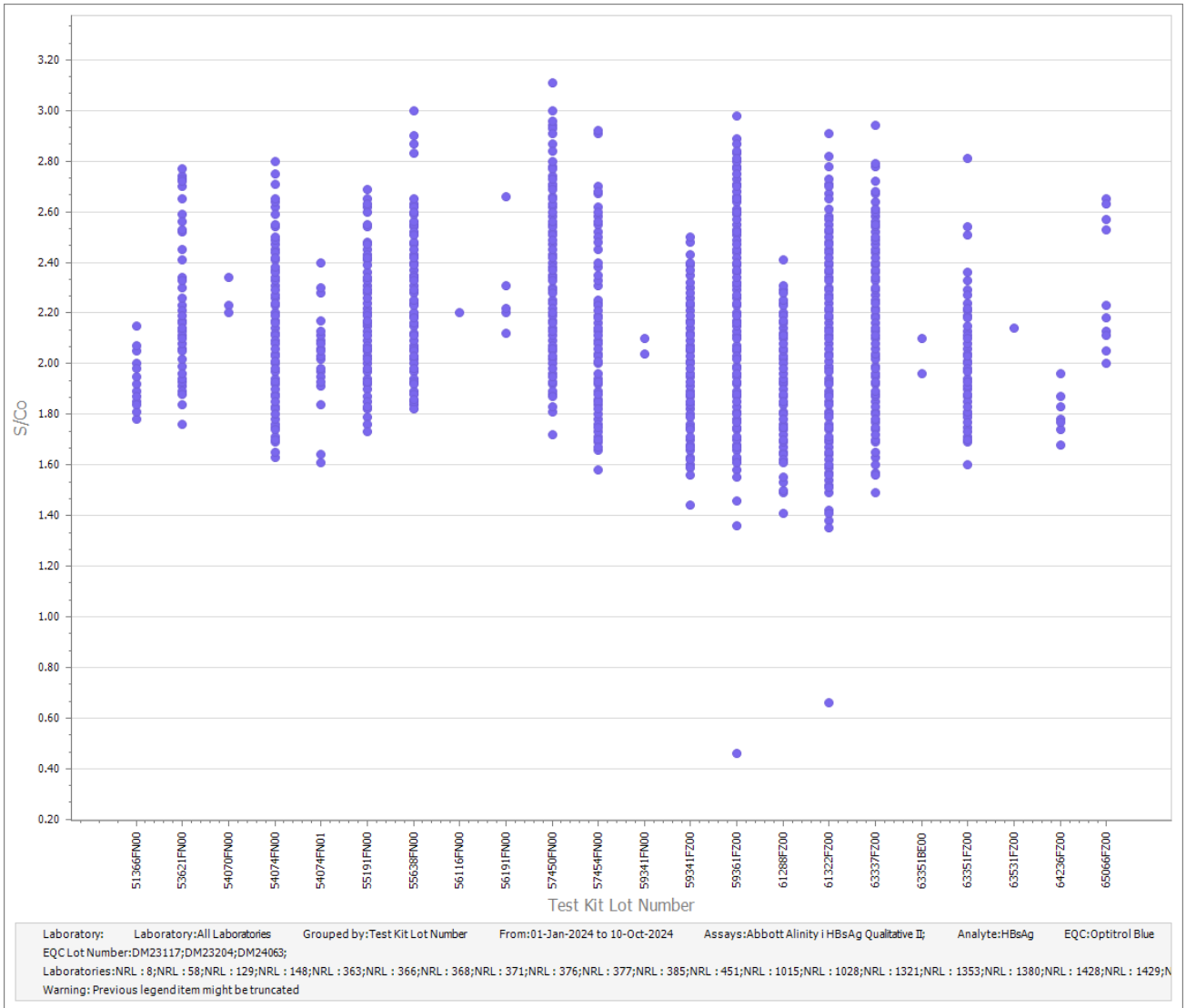


Figure 49 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i HBsAg Qualitative II assay sorted by reagent lots.

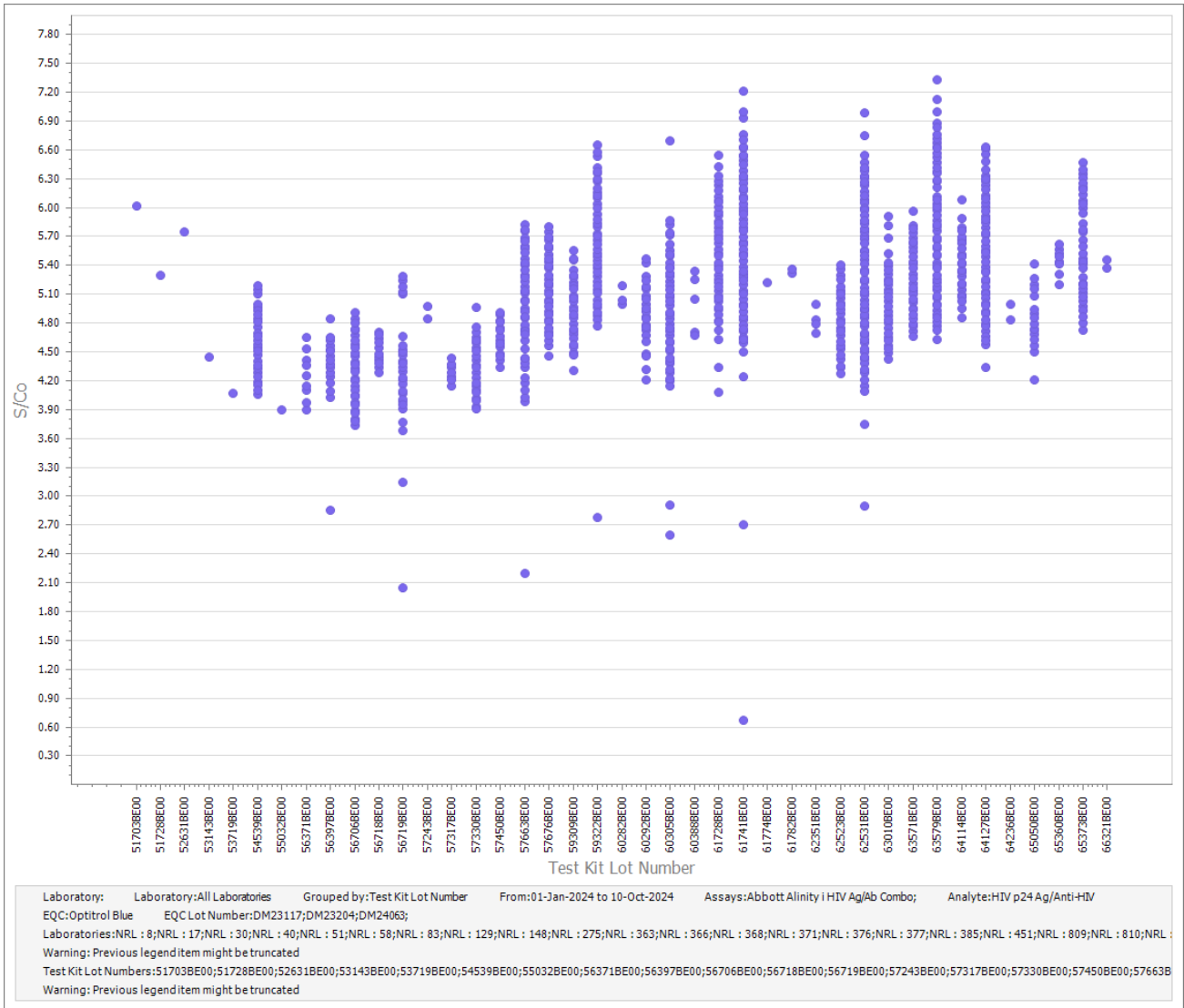


Figure 50 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i HIV Ag/Ab Combo assay sorted by reagent lots.

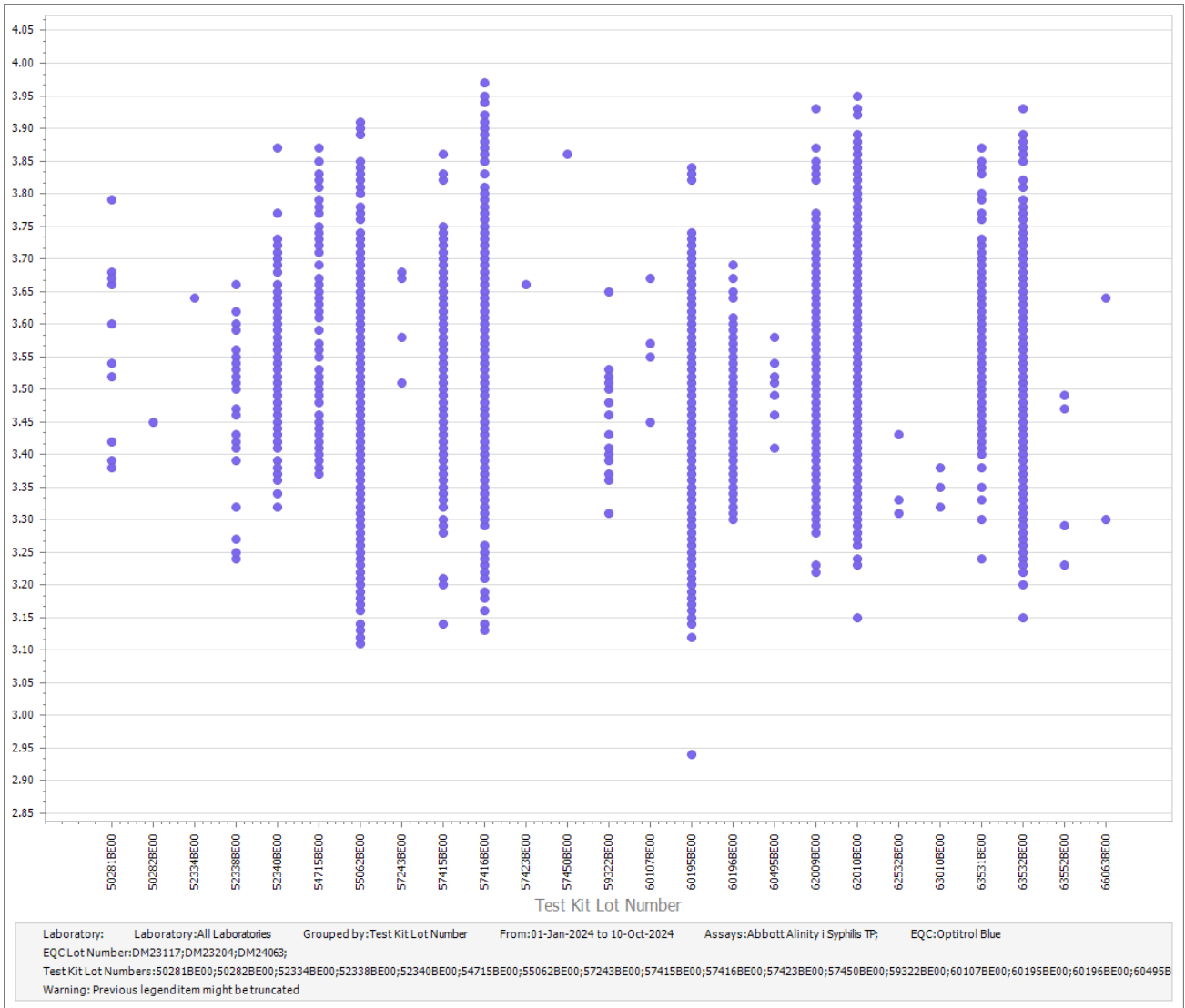


Figure 51 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Syphilis TP assay sorted by reagent lots.

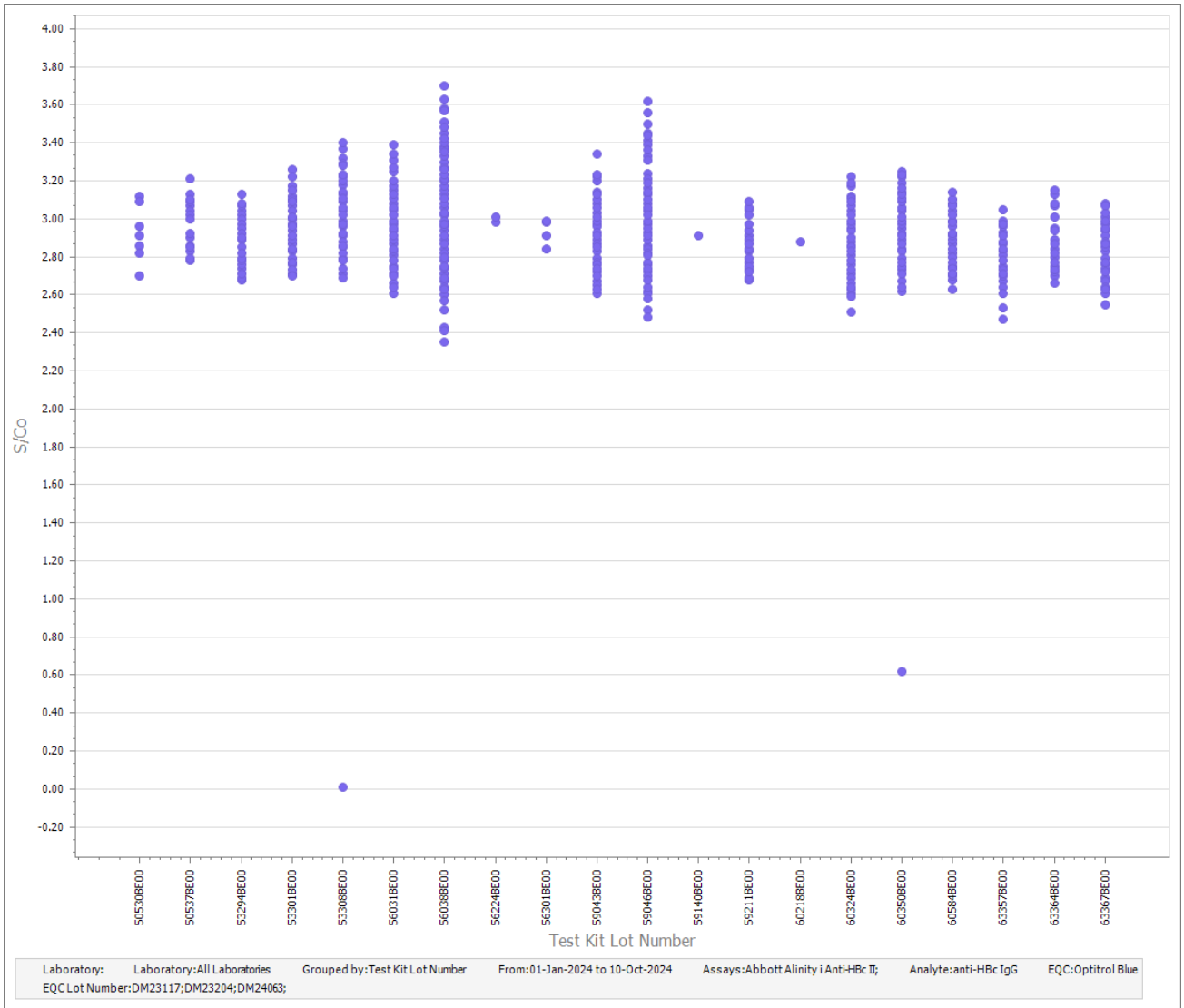


Figure 52 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity i Anti-HBc II assay sorted by reagent lots.

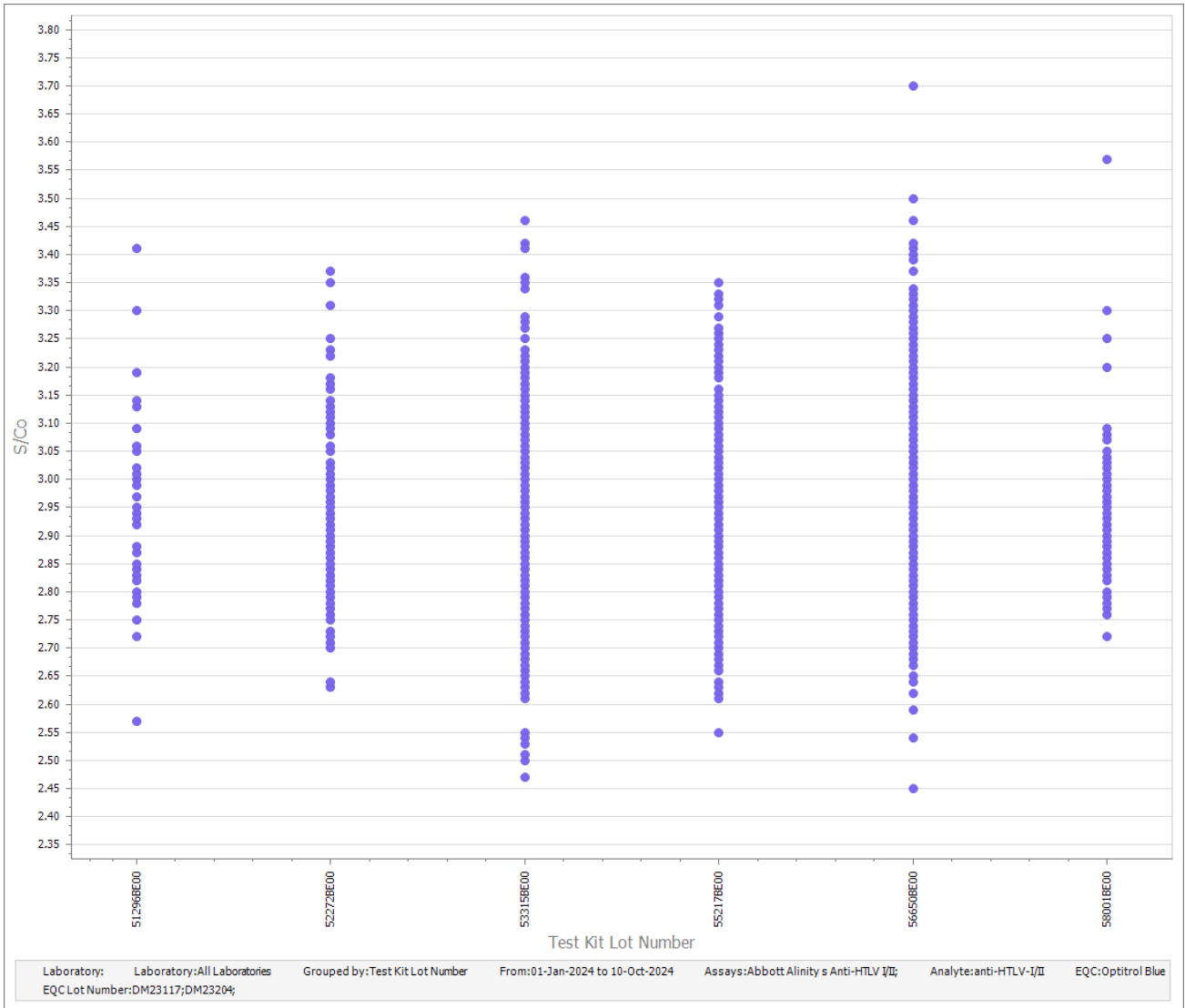


Figure 53 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott Alinity s Anti-HTLV I/II assay sorted by reagent lots.

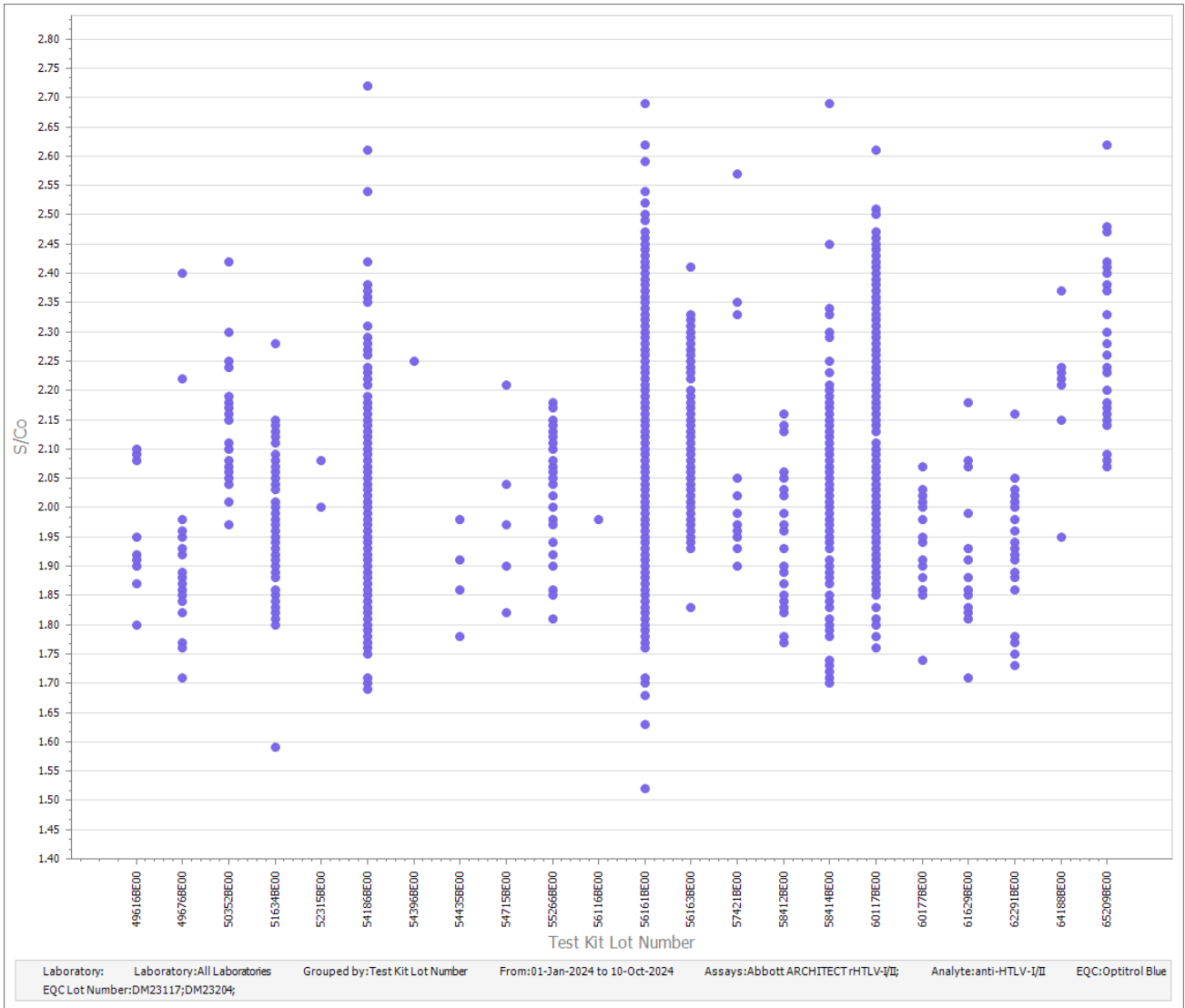


Figure 54 – Peer group data for Optitrol Blue lot DM23117 and related production lots, DM23204 and DM24063 when tested on Abbott ARCHITECT rHTLV-I/II assay sorted by reagent lots.