

QC Services Investigation: PMM-QC-2585

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and distributed in the week beginning 2025/SEPT/29

INTRODUCTION

During routine review of data submitted to EDCNet it was observed that Optitrol Yellow DM24064 data were reported below the NRL QConnect Range when testing on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lots 71610BE00 and 73319BE00. NRL investigated all peer group for data submitted to EDCNet for Optitrol Yellow and Abbott Kit positive controls for the Alinity s HIV Ag/Ab Combo assay (Alinity s HIV assay).

FINDINGS

This investigation looked at all peer group data reported to EDCNet for all Optitrol Yellow lots and Abbott kit controls on the two reagent lots, 71610BE00 and 73319BE00, to establish whether the variation was observed for any other reagent lot. Below is the full list of charts included in the investigation.

- Figure 1: Data reported on the Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM24064, by Participant
- Figure 2: Data reported on the Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM24064, by reagent lot.
- Figure 3: Data reported on the Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM23165, by Participant.
- Figure 4: Data reported on the Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM23165, by reagent lot.
- Figure 5: Mean plot for Abbott kit positive 1 control on the Alinity s HIV Ag/Ab Combo assay, by reagent lot.
- Figure 6: Mean plot for Abbott kit positive 2 control on the Alinity s HIV Ag/Ab Combo assay, by reagent lot.
- Figure 7: Mean plot for Abbott kit positive 3 control on the Alinity s HIV Ag/Ab Combo assay by reagent lot.
- Figure 8: Mean plot for Abbott kit positive 4 control on the Alinity s HIV Ag/Ab Combo assay, by reagent lot.
- Figure 9: Participant 1 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.
- Figure 10: Participant 3 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.
- Figure 11: Participant 5 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.
- Figure 12: Participant 11 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.
- Figure 13: Participant 335 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 73319BE00.
- Figure 14: Participant 446 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.
- Figure 15 Participant 382 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM23165 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

- Figure 16: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM25043, by Participant.
- Figure 17: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM25043, by reagent lot.
- Figure 18: QC Mean/Scatter plot of Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 data by reagent lot, reported for the Abbott Alinity s HIV Ag/Ab Combo.
- Table 1: Mean of Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 data by reagent lot reported for the Abbott Alinity s HIV Ag/Ab Combo.

DISCUSSION

Figures 1 & 2, 3 & 4 and 16 & 17 show data for the peer group demonstrating the performance of Optitrol Yellow lots DM24064, DM23165 and DM25043, respectively, when tested with the Alinity s HIV assay grouped by both participant and reagent lot.

Data reported for Optitrol Yellow lot DM24064 were observed as below the lower QConnect range when tested with the reagent lots 71610BE00 and 73319BE00 on the Alinity s HIV assay (Figures 1 - 2, 9 - 14). Data reported for Optitrol Yellow lot DM23165 were also observed below the NRL QConnect limit when tested with the reagent lot 71610B00 (Figure 15) and for Optitrol Yellow lot DM25043 when tested with the reagent lot 73319B00 on the Alinity s HIV assay (Figure 15).

Participant 382 (Figure 15) had reported data for Optitrol Yellow DM23165 with a subsequent reagent lot (74642BE00). Data reported for this new reagent lot were observed with S/Co values consistent with values reported prior to the use of either lots 71610BE00 and / or 73319BE00 and were within established QConnect limits.

Table 1 shows the mean S/Co data for each reagent lot for all Optitrol Yellow lots in use (DM23045, DM23165, DM24064 and DM25043). Reagent lots 71610B00 and 73319BE00 were observed to have lower mean values (3.73 S/Co and 4.19 S/Co, respectively) when compared with the mean values of previously and subsequently tested reagent lots, which all had a mean > 5.0 S/Co.

Figures 5 through 8 illustrate the mean peer group plot for each of the Abbott kit positive controls (Positives 1, 2, 3 and 4) reported by reagent lot. Kit positive 1 control showed similar shifts down in mean S/Co for both 71610BE00 and 73319BE00 reagent lots (Figure 5) and kit positive 4 control showed a similar shift down for reagent lot 73319BE00 (Figure 8). Kit positive controls 2 and 3 illustrated some variation however this is consistent with previously observed variation.

NRL contacted Abbott GmbH (Germany) with these observations, requesting information on whether the shift down in data observed for Optitrol Yellow and Abbott kit positive controls when tested with reagent lots 71610BE00 and 73319BE00 was expected and whether this was expected to be ongoing with subsequent reagent lots. Abbott provided NRL with a CoA for each of the reagent lots in question which confirmed there had been an observed shift down for the anti-HIV-1 analyte (Positive 1 and Panel 2) on the CoA's. Abbott made no comment to NRL regarding the status of subsequent reagent lots or if this would likely be an ongoing shift or what, if any, changes or modifications were made to these impacted reagent lots.

NRL has recommended to Optitrol Yellow peer group participants that they contact their Abbott representative with these observations requesting reagent lot information and

recommendations on interpretation on the variation observed. It was communicated to NRL by some peer group participants that Abbott had communicated with them that Abbott Technical Support had reviewed manufacturing records associated with the two reagent lots in question and confirmed that these reagent lots showed lower results for PC1 compared to previous reagent lots, however these results were within specifications and the lots met release criteria, indicating lot to lot variation.

CONCLUSIONS

The shift down in S/Co values observed for reagent lots 71610BE00 and 73319BE00 on the Abbott Alinity s Ag/Ab Combo assay were a result of reagent lot variation. Currently, this variation is isolated to the two reagent lots identified in this investigation with subsequent lot data reported as per historical values and within established QConnect ranges. The root cause has not been confirmed by Abbott. However, variation of this type is typically linked to a component change that usually can be identified and changed if necessary. Whether there are any consequences to clinical sensitivity of the assay is up to the manufacturer to assess and report – this cannot be determined through QC use alone.

NRL will not include Optitrol Yellow data reported to EDCNet for reagent lots 71610BE00 and 73319BE00 in the calculation of QConnect Ranges as they are outside the historical performance of the assay. Without confirmation of the root cause, NRL maintains these two reagent lots in question are outside the historical peer group dataset.

RECOMMENDATIONS

NRL recommend participants contact their Abbott representative with any questions or concerns regarding the lower reacting reagent lots.

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

NRL recommends participants obtain and review Abbott Certificate of Analysis documents (CoA) for each reagent lot received as these can indicate a potential shift in performance.

NRL will continue to monitor the Abbott Alinity s HIV Ag/AB Combo assay.

For more information or to request assistance with calculating and setting Laboratory Limits please contact NRL at qconnect@nrlquality.org.au

APPENDIX

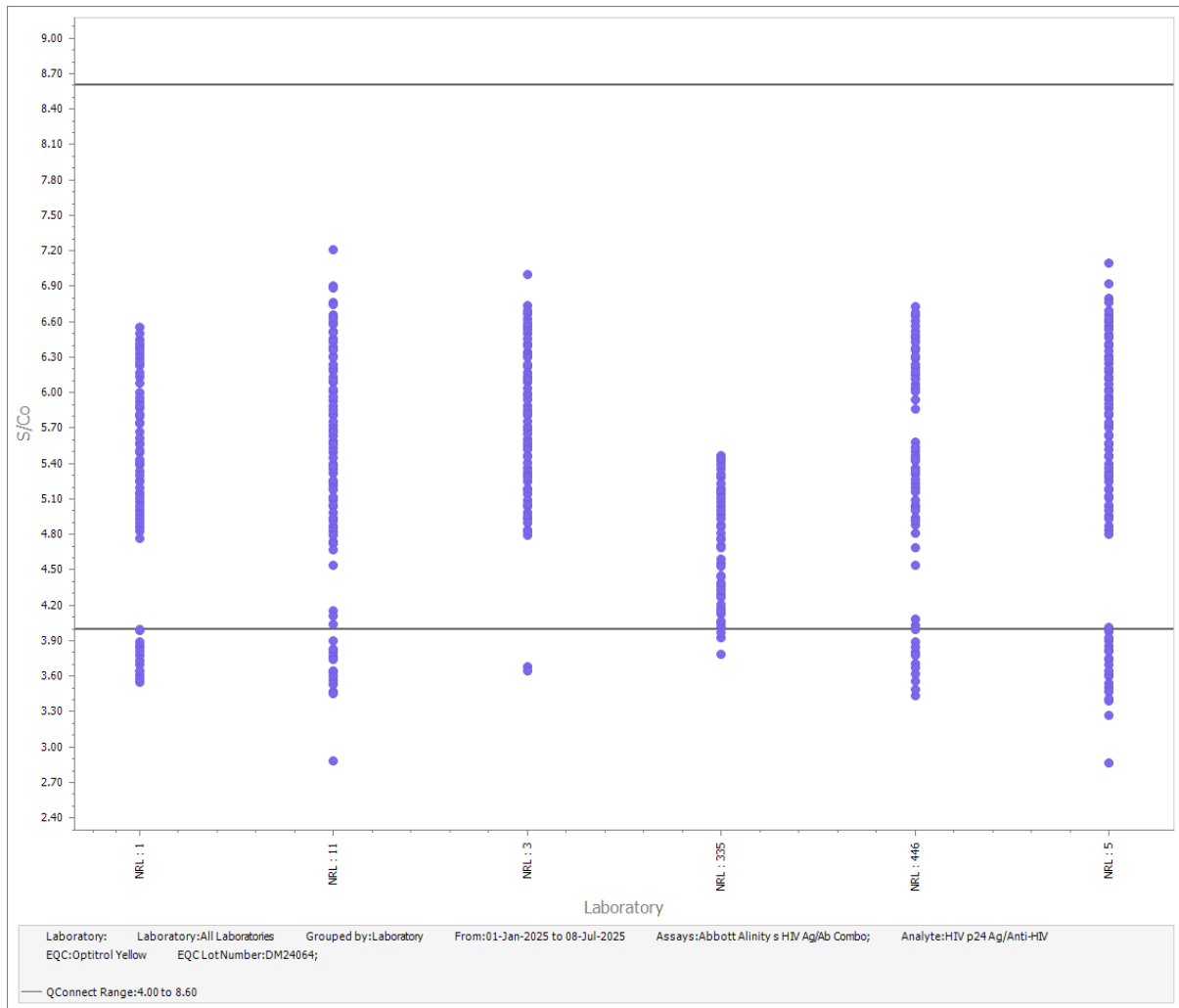


Figure 1: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM24064, by Participant

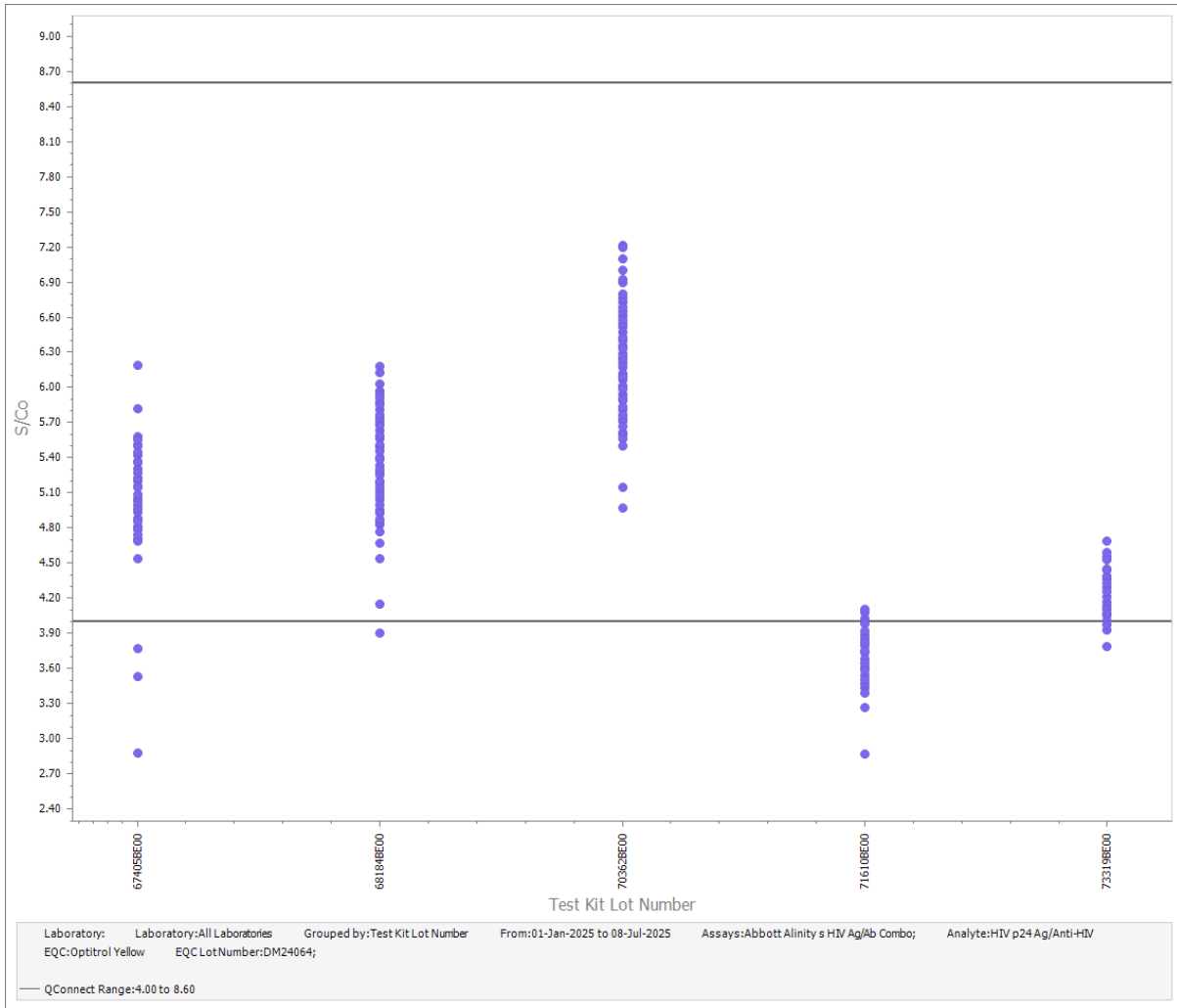


Figure 2: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM24064, by reagent lot.

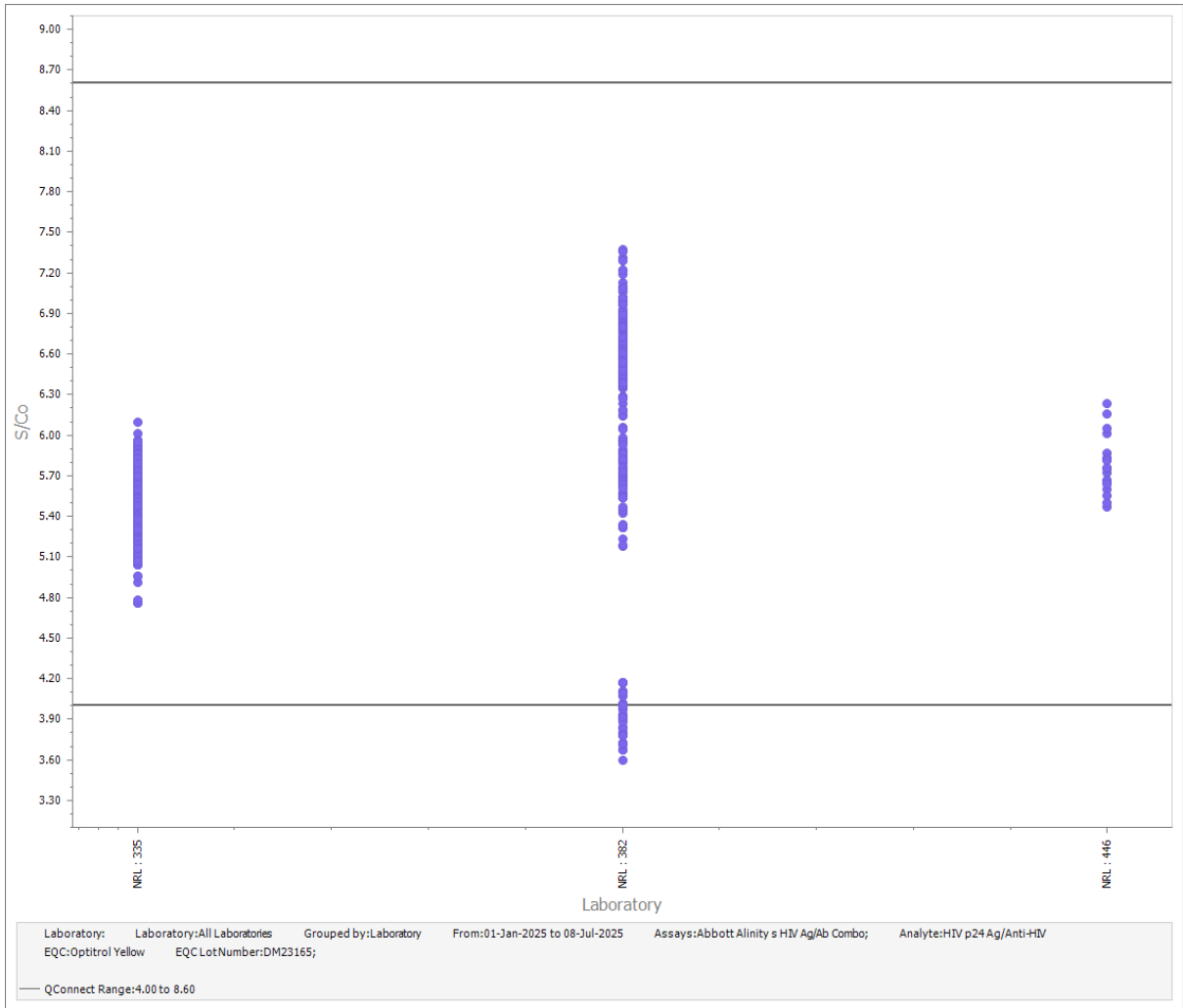


Figure 3: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM23165, by Participant.

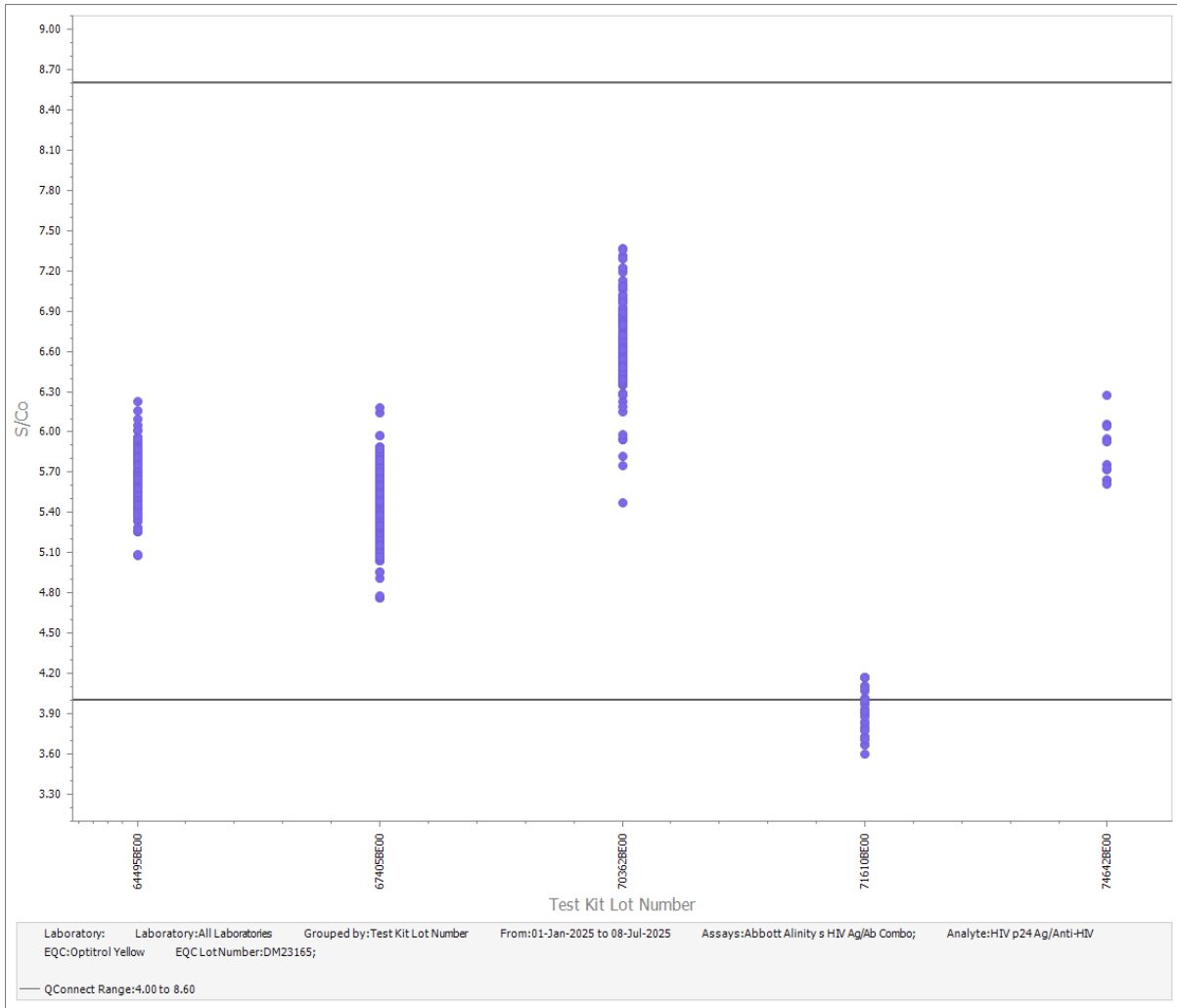
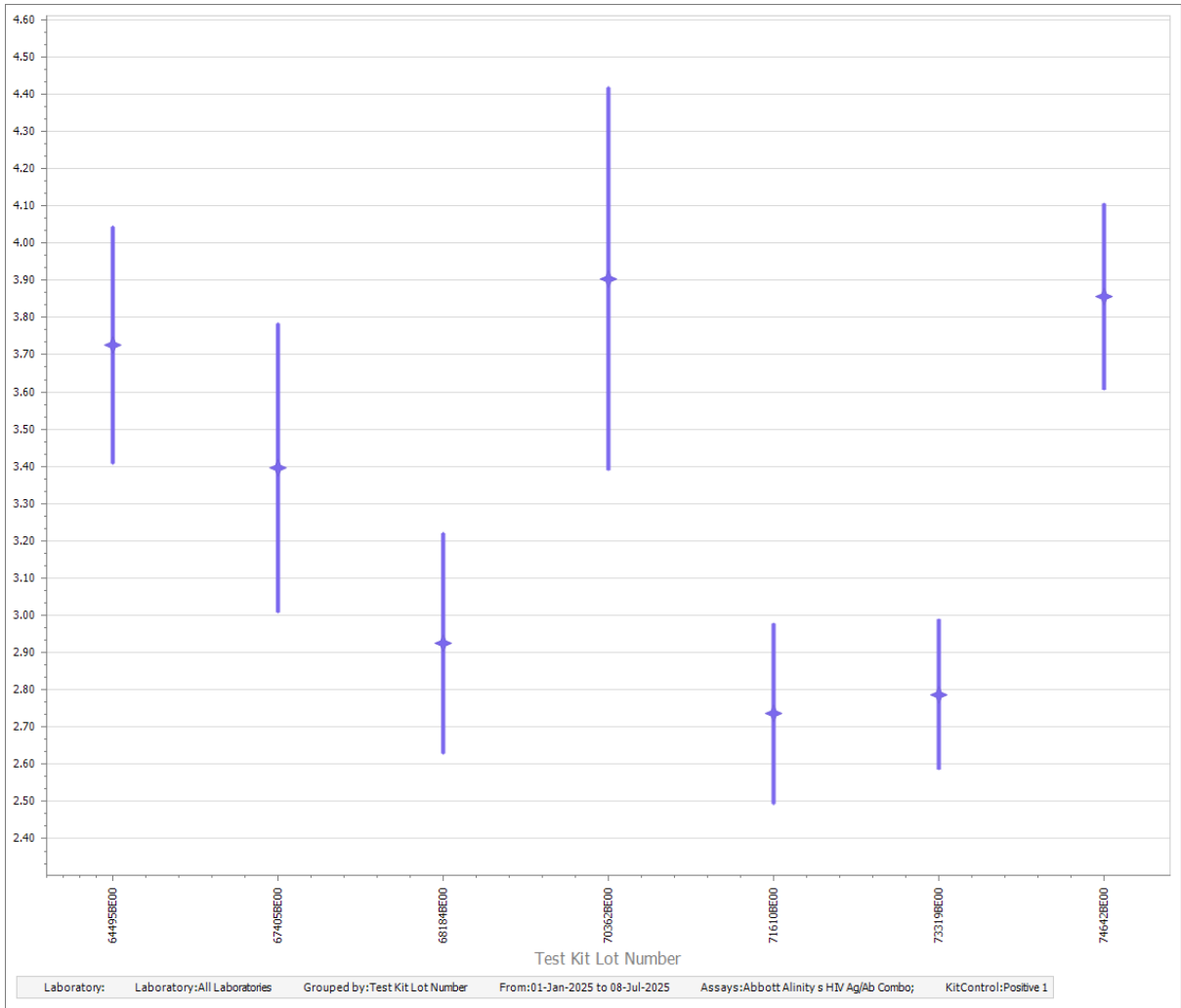
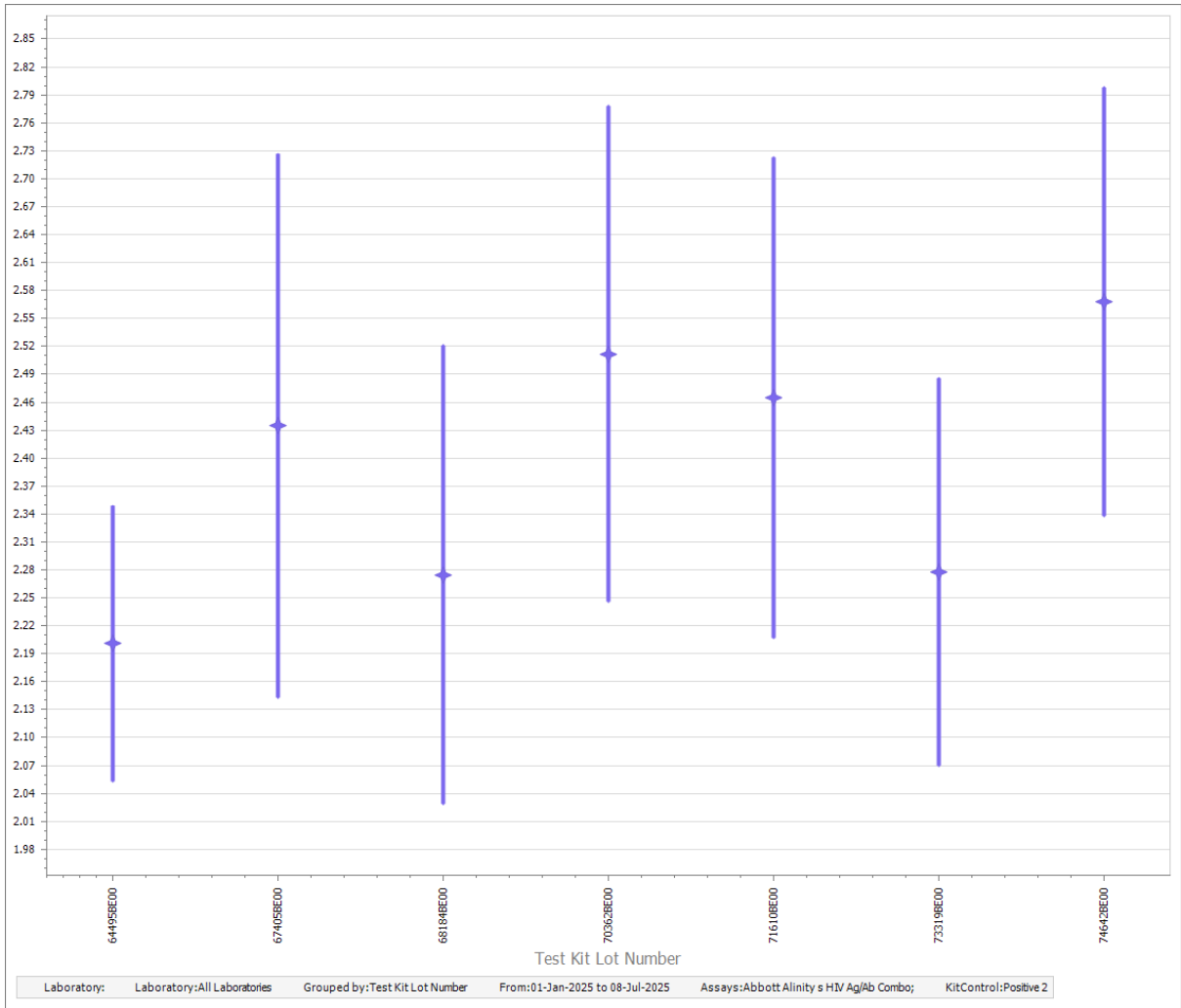
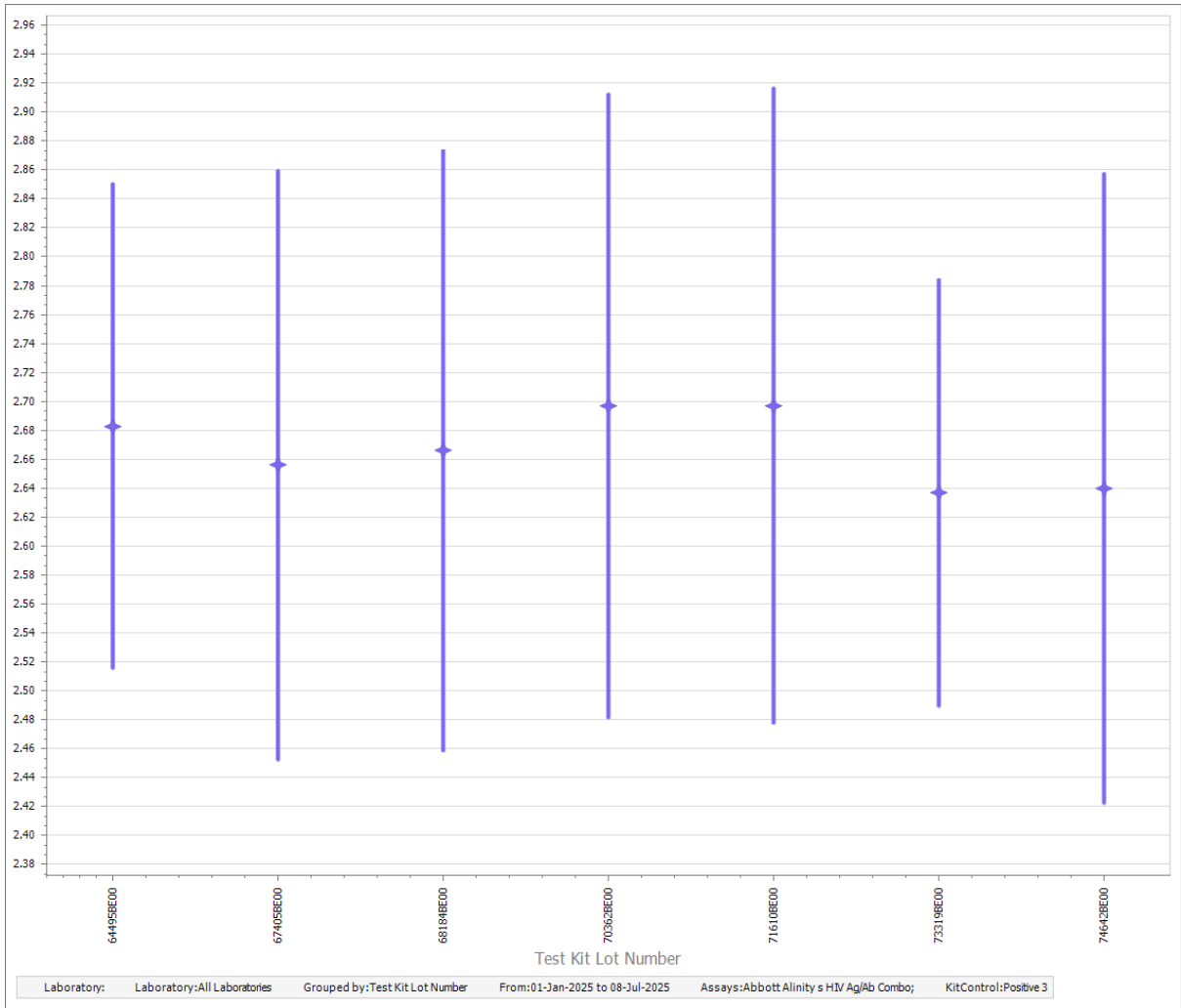
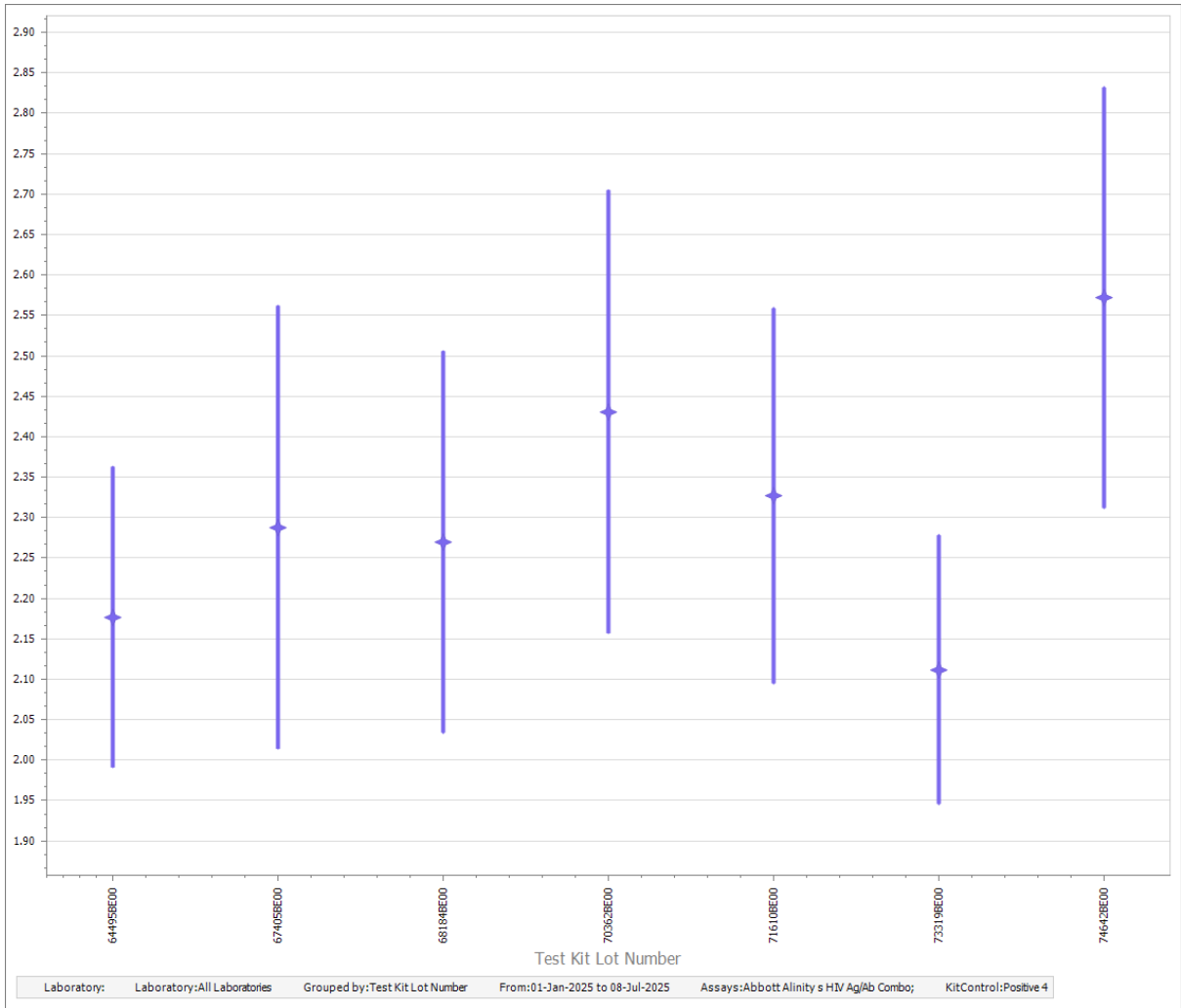


Figure 4: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM23165, by reagent lot.









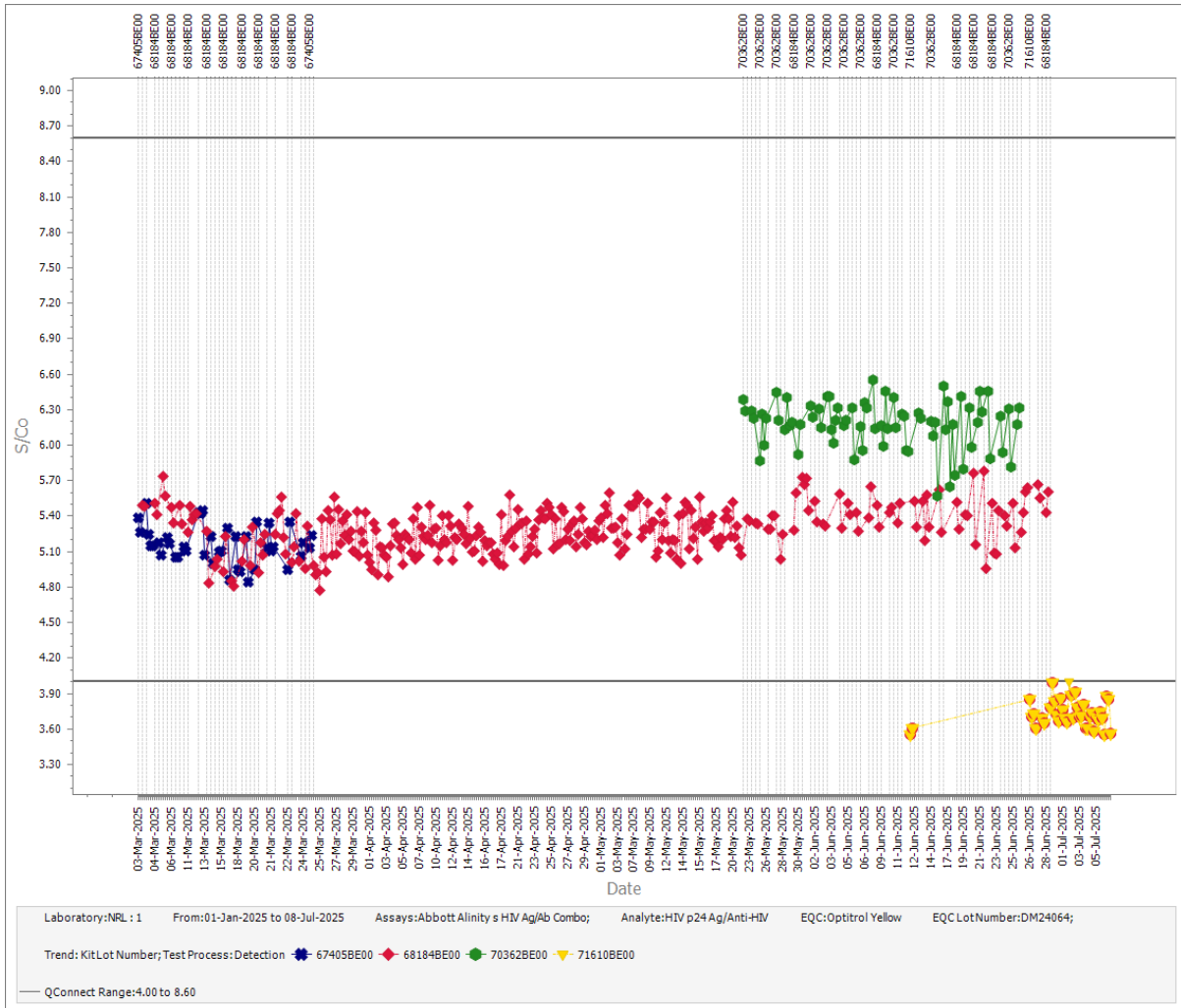


Figure 9: Participant 1 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

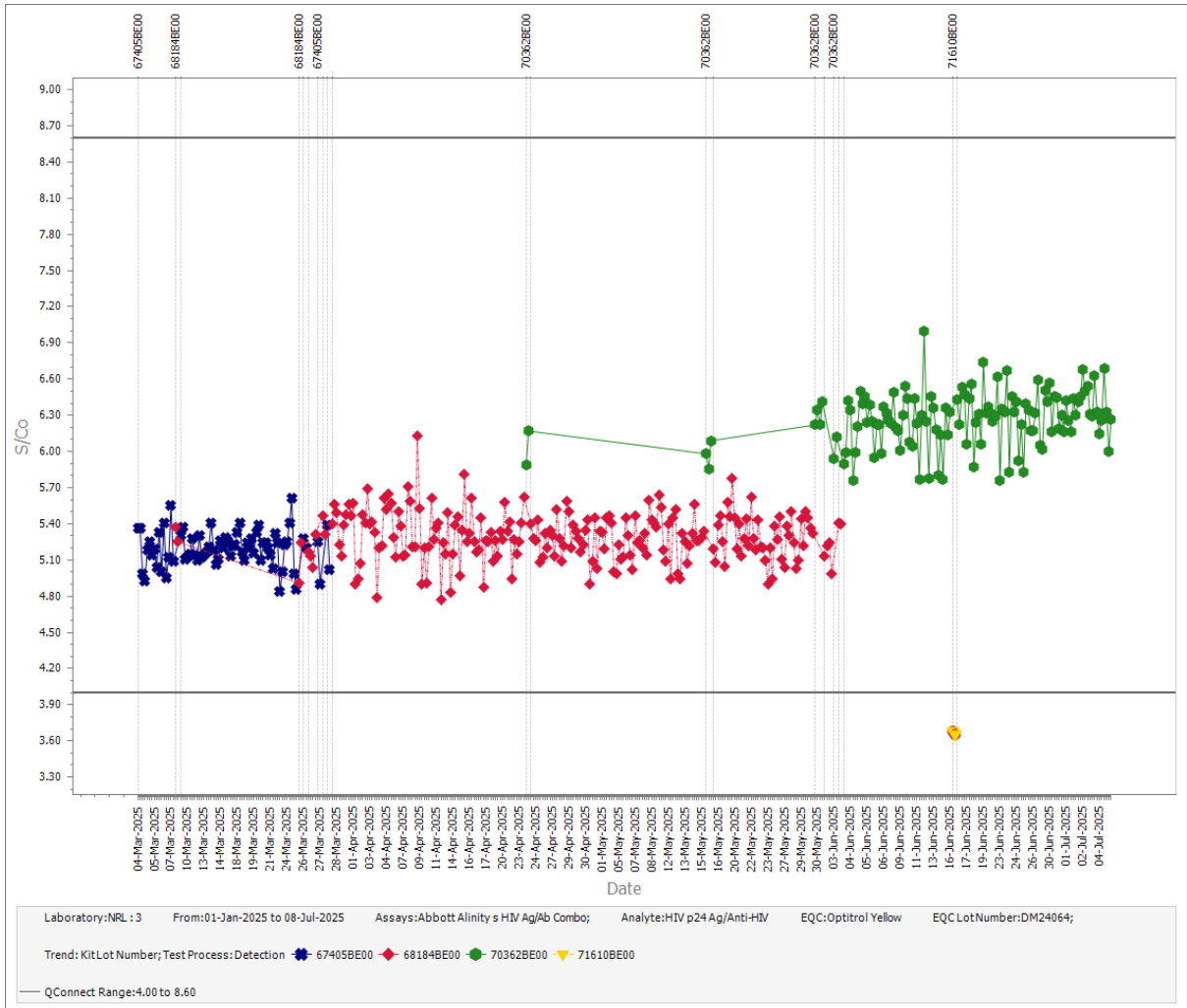


Figure 10: Participant 3 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

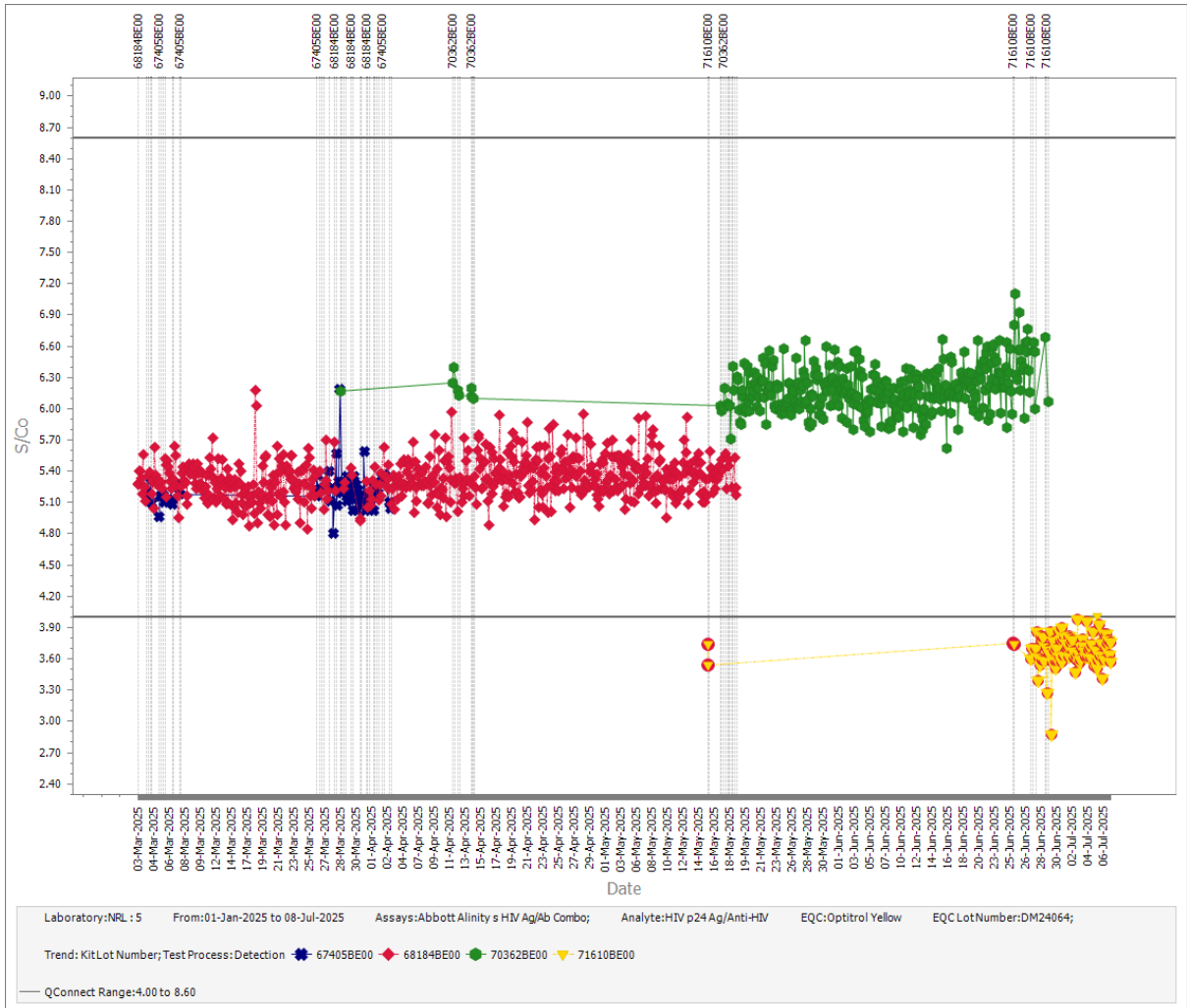


Figure 11: Participant 5 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

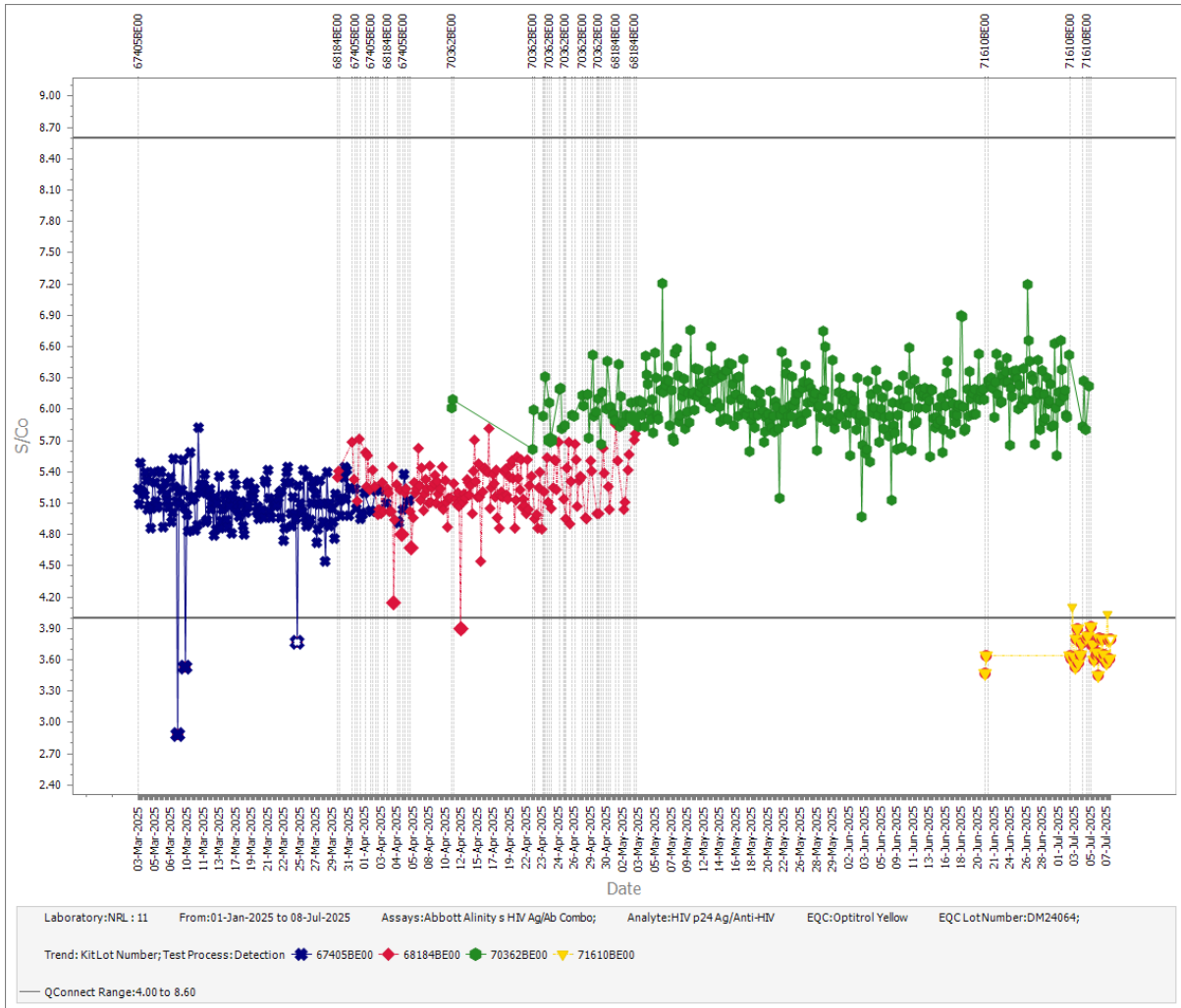


Figure 12: Participant 11 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

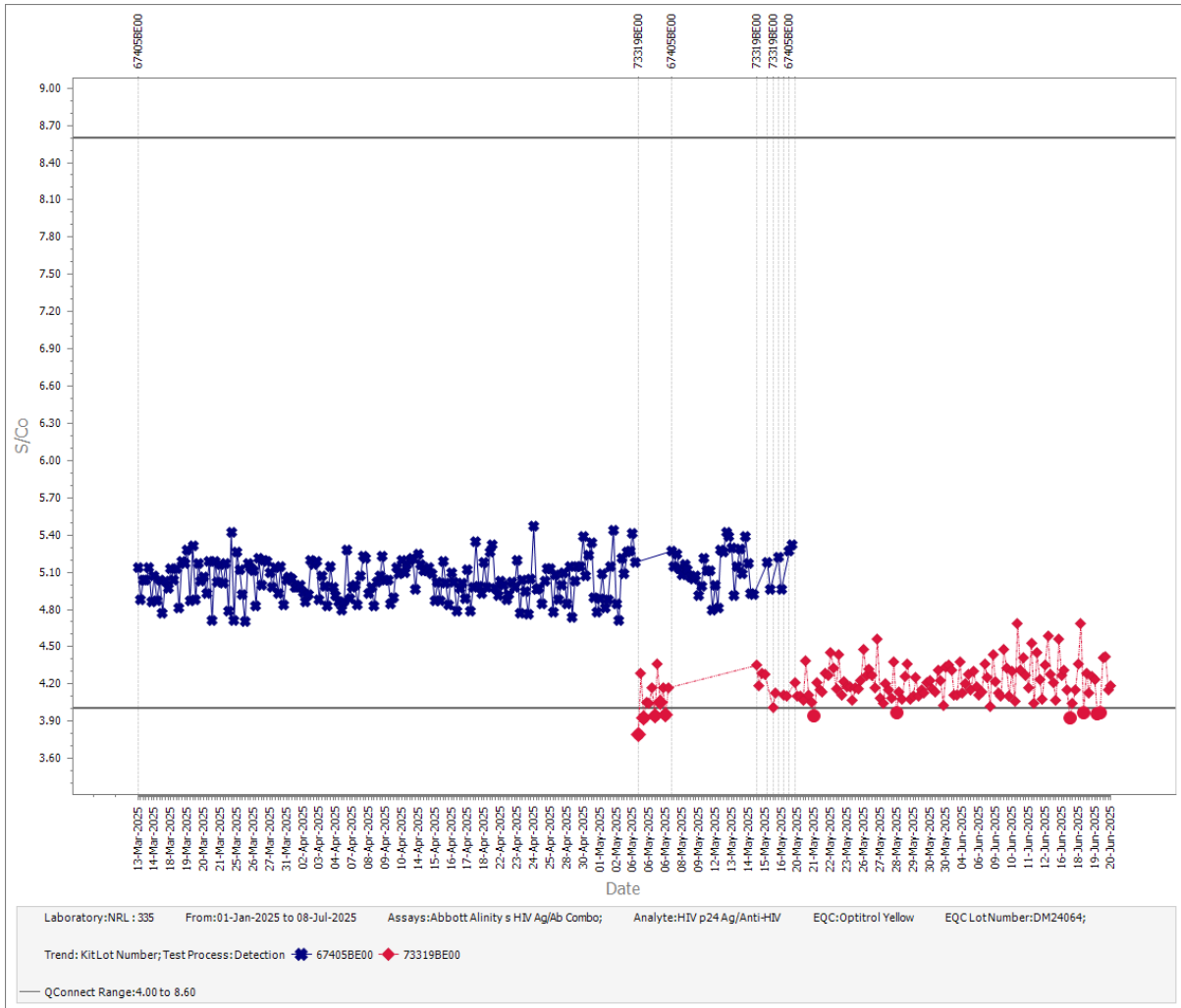


Figure 13: Participant 335 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 73319BE00.

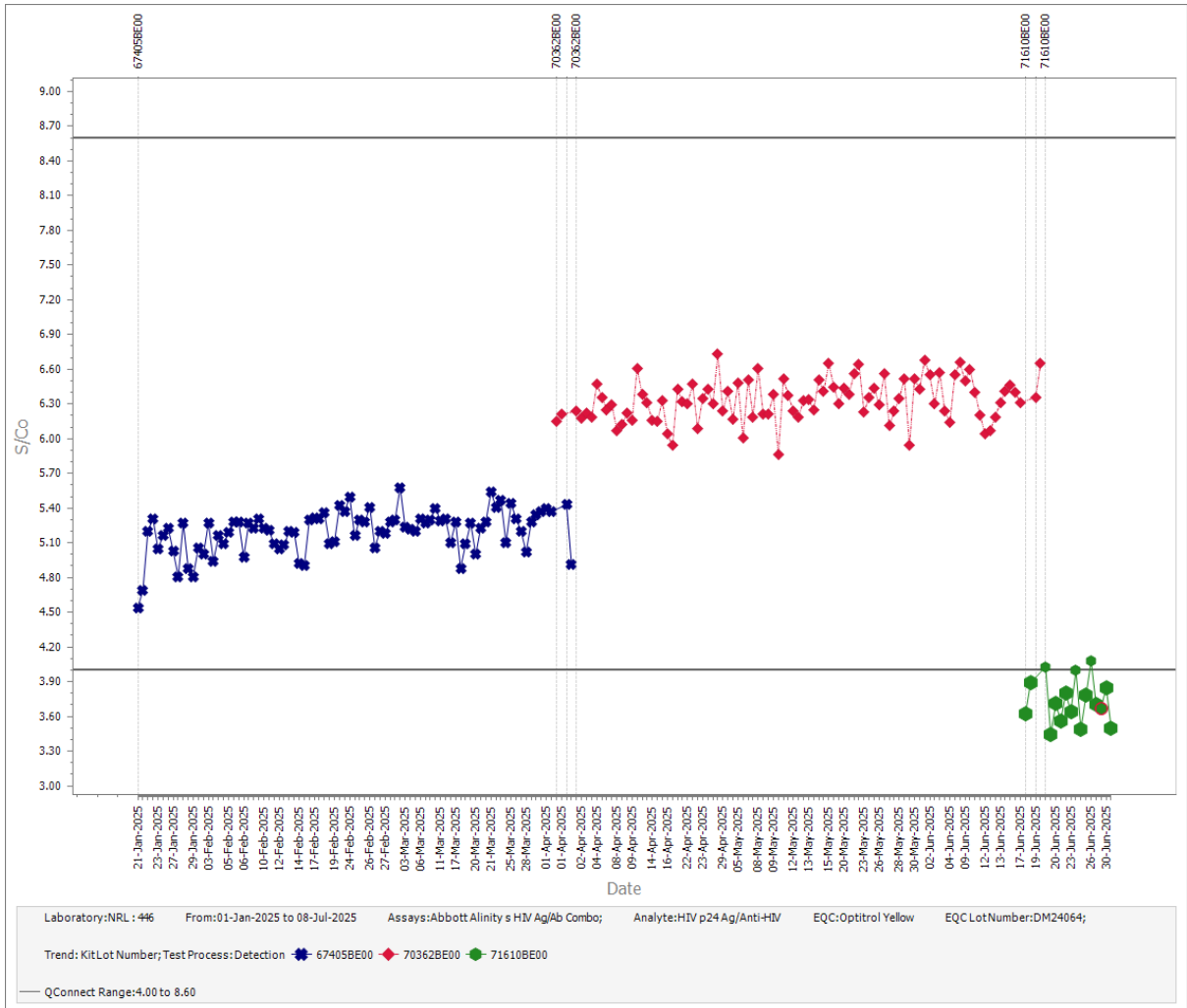


Figure 14: Participant 446 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM24064 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

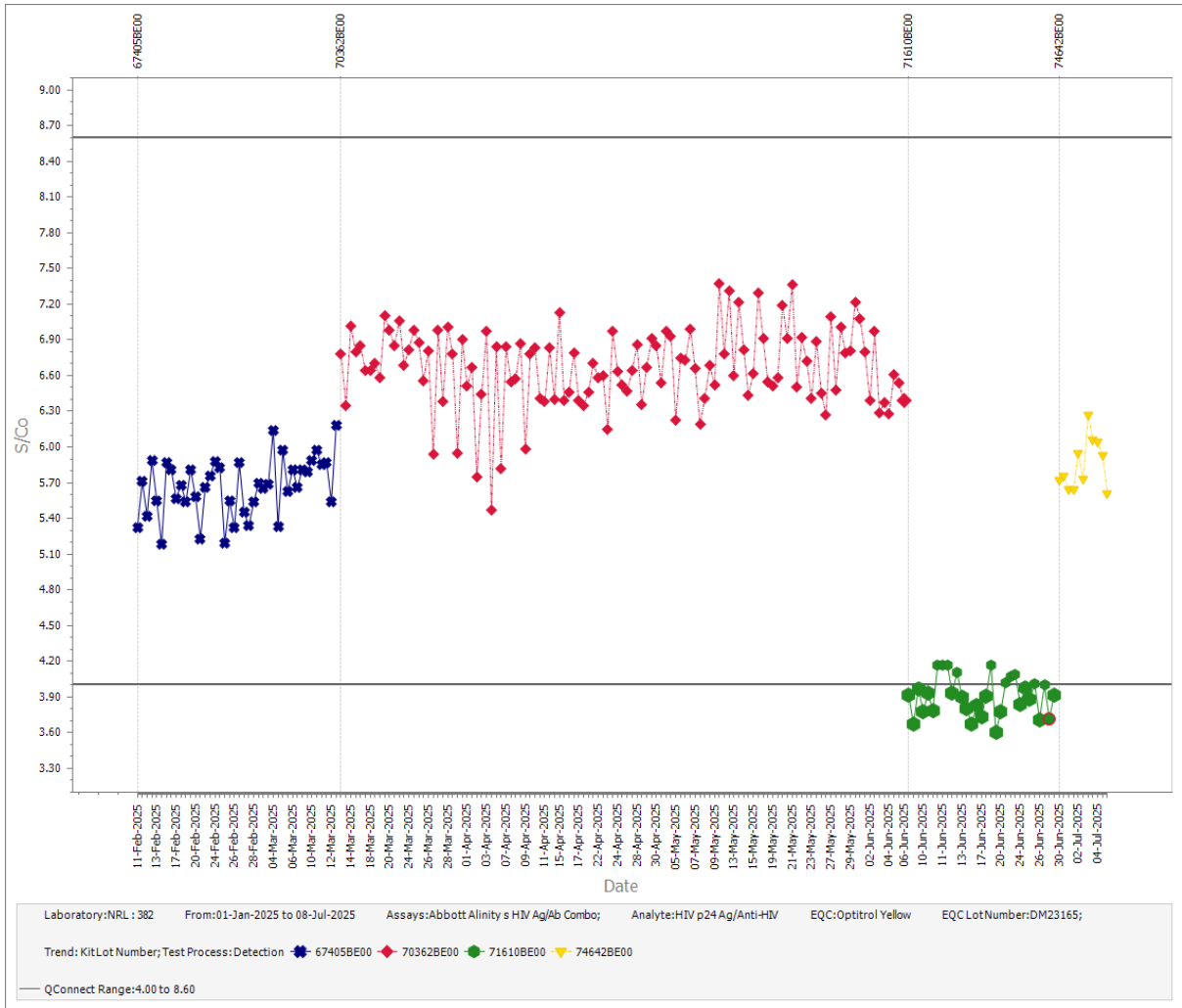


Figure 15: Participant 382 Levy Jennings chart grouped by reagent lot illustrating shift in data reported for Optitrol Yellow DM23165 on the Abbott Alinity s HIV Ag/Ab Combo assay for reagent lot 71610BE00.

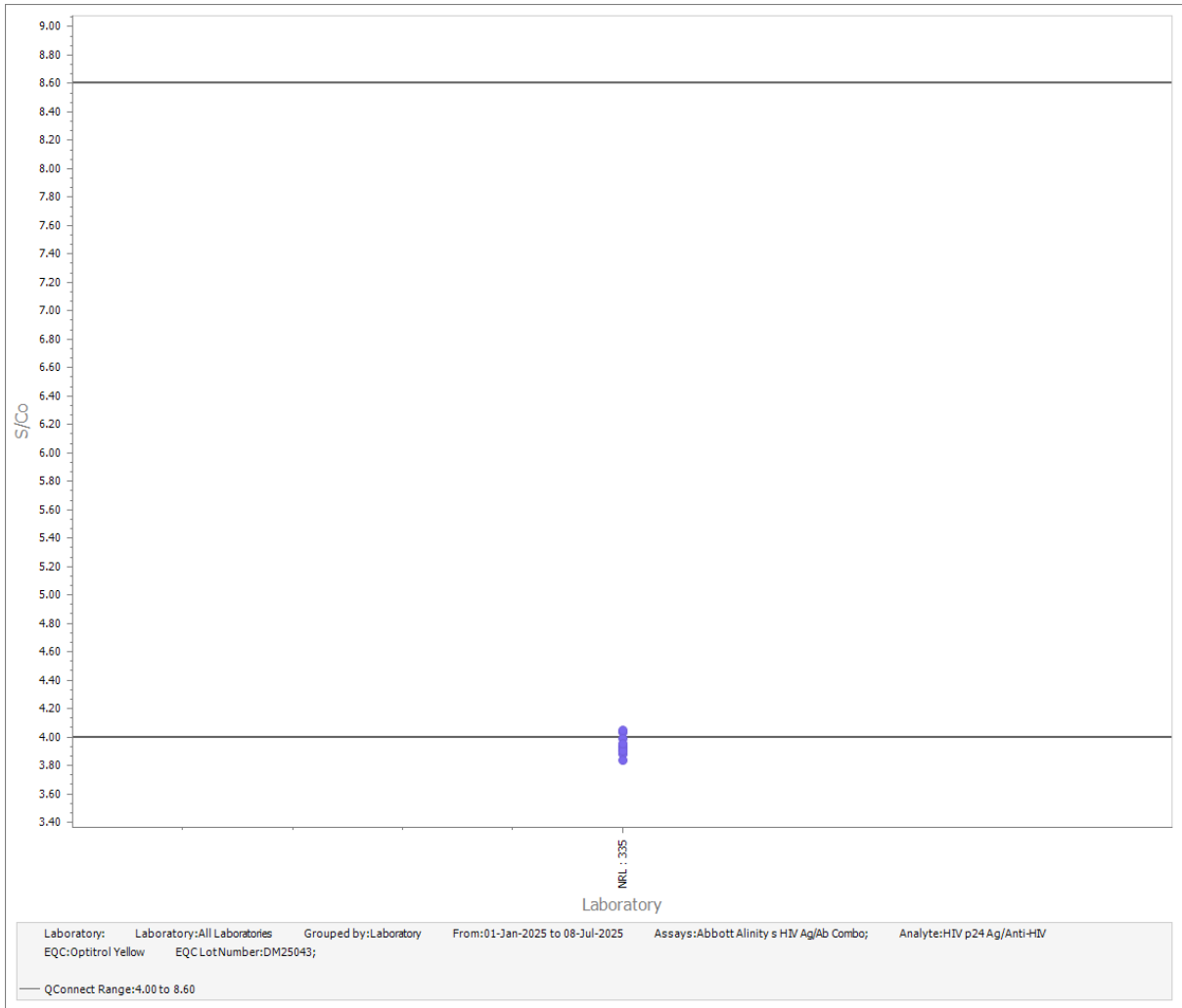


Figure 16: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM25043, by Participant.

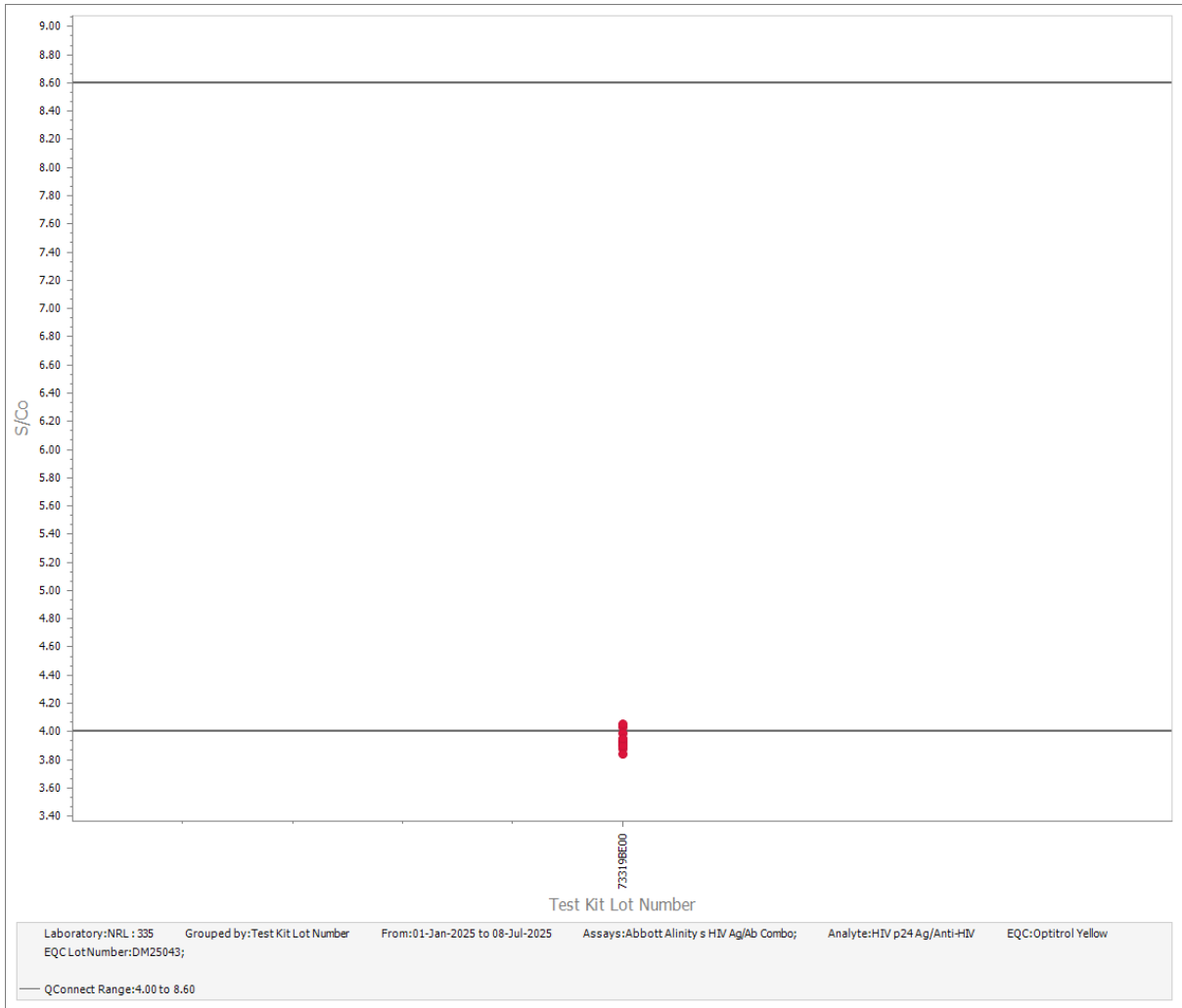


Figure 17: Data reported for Abbott Alinity s HIV Ag/Ab Combo assay for Optitrol Yellow DM25043, by reagent lot.

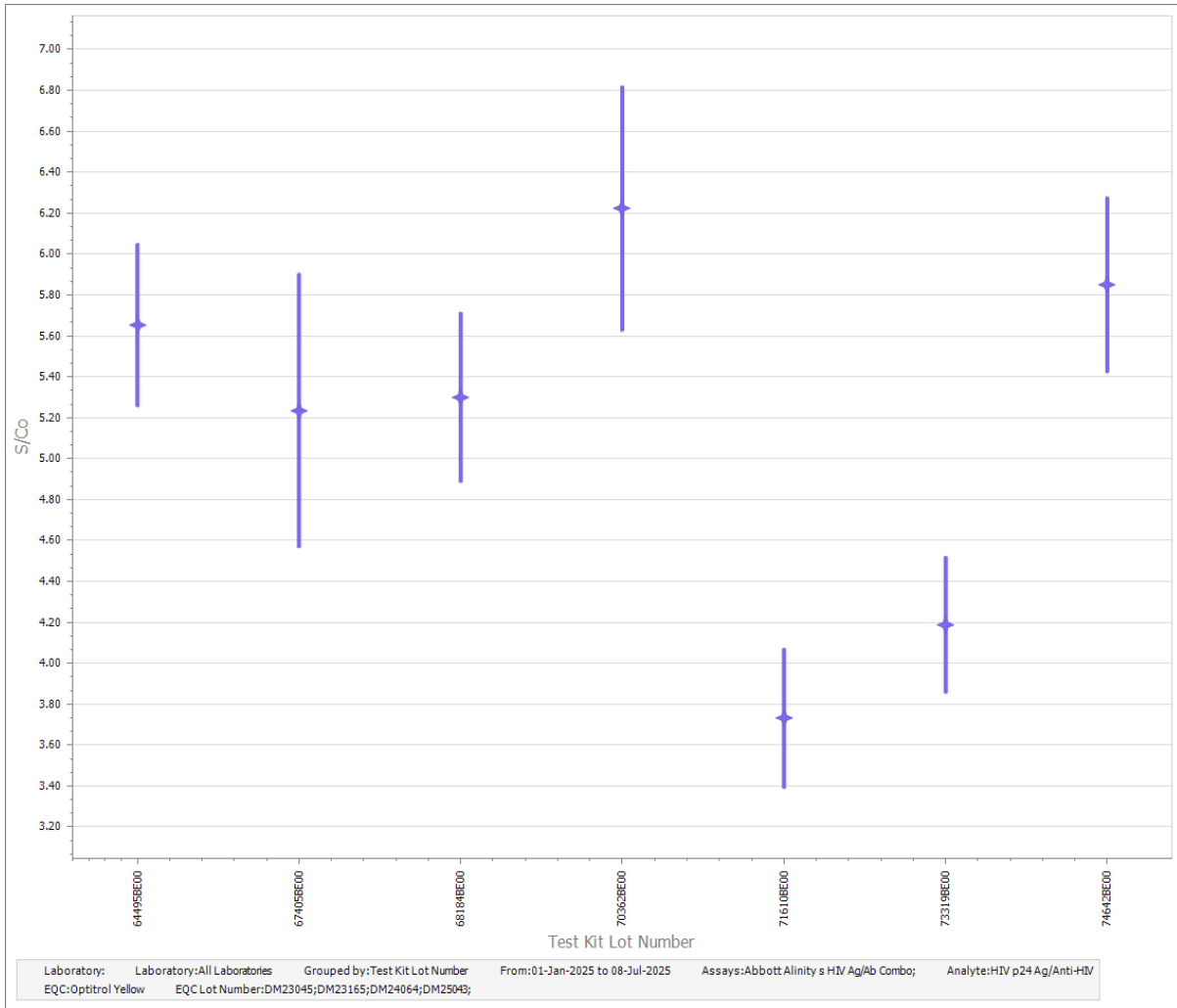


Figure 18: QC Mean/Scatter plot of Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 data by reagent lot, reported for the Abbott Alinity s HIV Ag/Ab Combo.

Table 1: Mean of Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 data by reagent lot reported for the Abbott Alinity s HIV Ag/Ab Combo.

Test Kit Lot Number	n	Mean	SD	x-2SD	x+2SD	Min	Max	CV(%)
64495BE00	127	5.65	0.20	5.26	6.05	5.08	6.23	3.52
67405BE00	881	5.24	0.34	4.57	5.91	2.88	7.02	6.40
68184BE00	1282	5.30	0.21	4.88	5.72	3.90	6.18	3.92
70362BE00	1129	6.22	0.30	5.63	6.82	4.97	7.37	4.80
71610BE00	205	3.73	0.17	3.39	4.07	2.87	4.17	4.58
73319BE00	146	4.19	0.17	3.85	4.52	3.79	4.69	3.99
74642BE00	11	5.85	0.21	5.42	6.28	5.61	6.27	3.66