

Optitrol Yellow Summary Report

January 2024 – July 2025

For Participants testing with Abbott Alinity s

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and distributed in the week beginning 2025OCT13

INTRODUCTION

In early 2022 Abbott released a new anti-HCV assay for the Alinity s platform (Abbott Alinity s Anti-HCV II) and it was observed that the previously recommended Optitrol product - Optitrol Blue, designed and manufactured for the Abbott ARCHITECT, Alinity i and Alinity s platforms - was not performing as expected on the new Alinity s Anti-HCV II assay. In response a new product - Optitrol Yellow - was designed and manufactured by DiaMEx, in partnership with NRL, and specifically recommended for use on the Abbott Alinity s platform. Participants commenced reporting Optitrol Yellow data to EDCNet from early 2022 with the Australian Red Cross Lifeblood of Processing Centres (Lifeblood network) switching from testing Optitrol Blue on their Alinity s anti-HCV assays in March 2025 following the release of the Alinity s Anti-HCV II assay version in Australia. This report provides a summary of peer group performance for all Alinity s since January 2024 for Optitrol Yellow.

FINDINGS

- Figure 1 – Peer Group, Abbott Alinity s Anti-HCV II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.
- Figure 2 – Peer Group, Abbott Alinity s Anti-HCV II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.
- Figure 3 – Peer Group, Abbott Alinity s Anti-HTLV I/II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.
- Figure 4 – Peer Group, Abbott Alinity s Anti-HTLV I/II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.
- Figure 5 – Peer Group, Abbott Alinity s HBsAg testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.
- Figure 6 – Peer Group, Abbott Alinity s HBsAg testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.
- Figure 7 – Peer Group, Abbott Alinity s HIV Ab/Ag Combo testing with Optitrol Yellow Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant. Reagent lot numbers 71610BE00 and 73319BE00 are excluded from chart.
- Figure 8 – Peer Group, Abbott Alinity s HIV Ab/Ag Combo testing with Optitrol Yellow Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.
- Figure 9 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM23045 and DM23165 by Participant.
- Figure 10 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM23045 and DM23165 by Reagent Lot.
- Figure 11 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM24064 and DM25043 by Participant.
- Figure 12 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM24064 and DM25043 by Reagent Lot.

DISCUSSION

Peer group data were reviewed from 1 January 2024 through to 31 July 2025 for Optitrol Yellow when tested on the Alinity s platform for the Alinity s Anti-HCV II, Alinity s Anti-HTLV I/II, Alinity s HBsAg, Alinity s HIV Ag/Ab Combo and Alinity s Syphilis assays (Abbott Laboratories, Abbott Park, IL, USA). Manufacturing changes were made to Optitrol Yellow DM23045 (New bulk stock for HTLV) and DM24064 (Syphilis stock change and additional anti-HBc added). The findings are discussed below.

Abbott Alinity s Anti-HCV II –

Eight participants reported data to EDCNet for four Optitrol Yellow lot numbers (DM23045, DM23165, DM24064 and DM25043) and 15 reagent lots for the reviewed period for the Alinity

s Anti-HCV II (Figures 1 and 2). QConnect Limits of 2.00 – 3.00 S/Co for all four Optitrol Yellow lot numbers tested with. A mean of 2.40 S/Co and SD 0.14 for total of 6805 results and an out-of-range percentage of 0.84 %. Data outside the QConnect Limits for all Participants were reviewed for patterns or trends with the root causes identified, where possible, as:

- Calibration
- Maintenance (i.e. pipettor probe)

For participants within the Lifeblood network, 3,112 results were reported for four reagent lots and one lot of Optitrol Yellow (DM24064). A combined mean of 2.37 S/Co, SD 0.16, % CV of 6.63 and out-of-range percentage of 1.57 % (49 results). 11 results were made invalid by NRL to exclude from QConnect Limit calculations due to investigation findings.

Abbott Alinity s Anti-HTLV I/II –

Three Optitrol Yellow lot numbers (DM23165, DM24064 and DM25043) were reported to EDCNet during the period selected for review for 10 reagent lot numbers across five participants for the Alinity s Anti-HTLV I/II assay (Figures 3 and 4). QConnect Limits of 2.40 – 3.40 S/Co for all three Optitrol Yellow lot numbers tested with a mean of 2.91 S/Co and SD 0.18 for a total of 3,372 results and an out-of-range percentage of 1.30%. Data outside QConnect Limits for all participants were reviewed for trends with the root causes identified, where possible, as:

- Calibration
- Maintenance (i.e. pipettor probe)

For participants in the Lifeblood network, 2,204 results were reported for six reagent lots and one lot of Optitrol Yellow (DM24064). A combined mean of 2.89 S/Co, SD 0.16, %CV of 5.65 and out-of-range percentage of 0.59% (13 results).

Abbott Alinity s HBsAg –

Eight participants reported data to EDCNet for four Optitrol Yellow lot numbers (DM23045, DM23165, DM24064 and DM25043) and 17 reagent lots for the reviewed period for the Alinity s HBsAg (Figures 5 and 6). QConnect Limits of 1.20 – 3.40 S/Co for all four Optitrol Yellow lot numbers tested with a mean of 2.09 S/Co and SD 0.28 for total of 7,031 results. All data reported to EDCNet were within QConnect Limits.

For participants in the Lifeblood network, 3,227 results were reported for seven reagent lots and one lot of Optitrol Yellow (DM24064). A combined mean of 1.95 S/Co, SD 0.14, %CV of 7.24.

Abbott Alinity s HIV Ag/Ab Combo –

Four Optitrol Yellow lot numbers (DM23045, DM23165, DM24064 and DM25043) were reported to EDCNet during the period selected for review for 12 reagent lot numbers across eight participants for the Alinity s HIV Ag/Ab Combo (Figures 7 and 8). QConnect Limits of 4.00 – 8.60 S/Co were applied to Optitrol Yellow lot DM23045 and 3.50 – 8.10 S/Co for the remaining three Optitrol Yellow lot numbers in use. An investigation report (PMM-QC-2585) for data reported below QConnect Limits for reagent lots 71610BE00 and 73319BE00 concluded that the lower reactivity was related to reagent lot variation and that with these two reagent lots would be excluded from QConnect Limits calculations. A mean of 5.58 S/Co and SD 0.51 for total of 7,387 results and an out-of-range percentage of 0.01 % were observed for

data reported on Optitrol Yellow (DM23045, DM23165, DM24064 and DM25043) when excluding reagent lots 71610BE00 and 73319BE00. Data outside QConnect Limits for all participants were reviewed for patterns or trends with the few root causes identified including:

- PMM-QC-2585 RLV investigation.
- Pipetting errors

For participants in the Lifeblood network, 3,210 results were reported for four reagent lots (including excluded reagent lot 71610BE00) and one lot of Optitrol Yellow (DM24064). Of the data obtained for the three reagent lots included in calculations, 2,635 results were reported with a combined mean of 5.61 S/Co, SD 0.50, % CV of 8.84 - and out-of-range percentage of 0.04 % (one result). One result was made invalid as it was repeated by the Participant.

Abbott Alinity s Syphilis –

Seven participants reported data to EDCNet for four Optitrol Yellow lot numbers (DM23045, DM23165, DM24064 and DM25043) and 10 reagent lots for the reviewed period on the Alinity s Syphilis (Figures 9 - 12). QConnect Limits were 2.30 – 3.50 S/Co for Optitrol Yellow lots DM23045 and DM23165 and at the time of this review, 3SD calculations of 2.88 – 3.90 S/Co were in place for Optitrol Yellow lots DM24064 and DM25043, due to the known syphilis stock material change from lot DM24064 onwards. For Optitrol Yellow DM23045 and DM23165, a mean of 2.77 S/Co and SD 0.14 for total of 1857 results and an out-of-range percentage of 0.32 %, across three Participants. For Optitrol Yellow lots DM24064 and DM25043, a mean of 3.39 S/Co and SD 0.17 for a total of 3,893 results and an out-of-range percentage of 1.28% were observed for data across seven participants. Data outside QConnect Limits and 3SD calculations for all participants were reviewed for trends with some identified root causes as:

- Instrument variation
- Calibrator lot number change
- Transcription error.

For participants in the Lifeblood network, 3,174 results were reported for six reagent lots and one lot of Optitrol Yellow (DM24064). A combined mean of 3.39 S/Co, SD 0.18, %CV of 5.20 and out-of-range percentage of 1.20% (38 results) were observed. A total of 16 results were made invalid by NRL to exclude them from QConnect Limit calculations due either to investigation findings or to being repeated as invalid by the participant.

CONCLUSION

Data reported for Optitrol Yellow shows the same expected consistency as the previous Optitrol product in use, Optitrol Blue. Lifeblood network data is consistent across the network and peer group with no isolated, unexplained or unresolved variation events reported.

APPENDIX

Abbott Alinity s Anti-HCV II

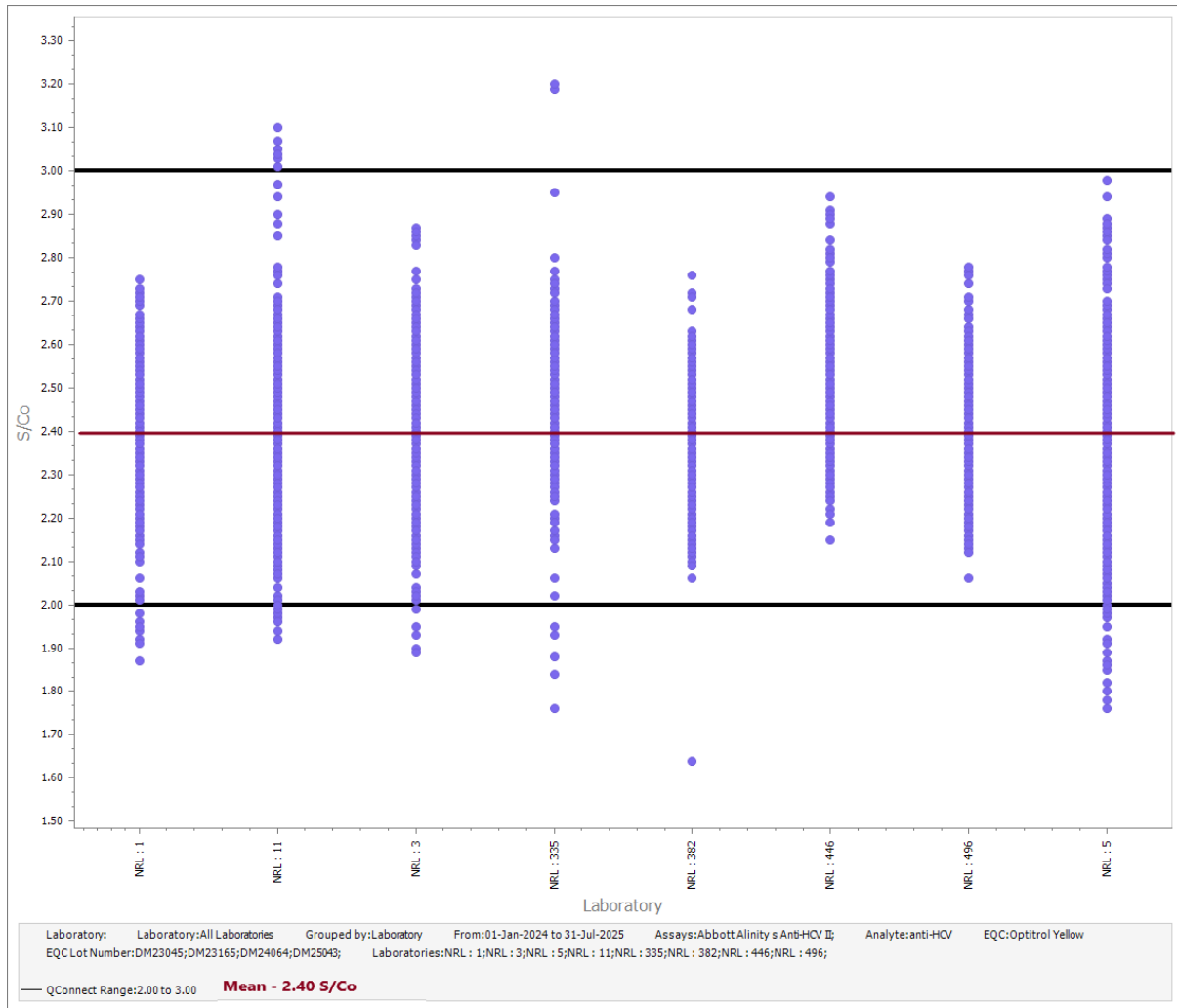


Figure 1 – Peer Group, Abbott Alinity s Anti-HCV II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.

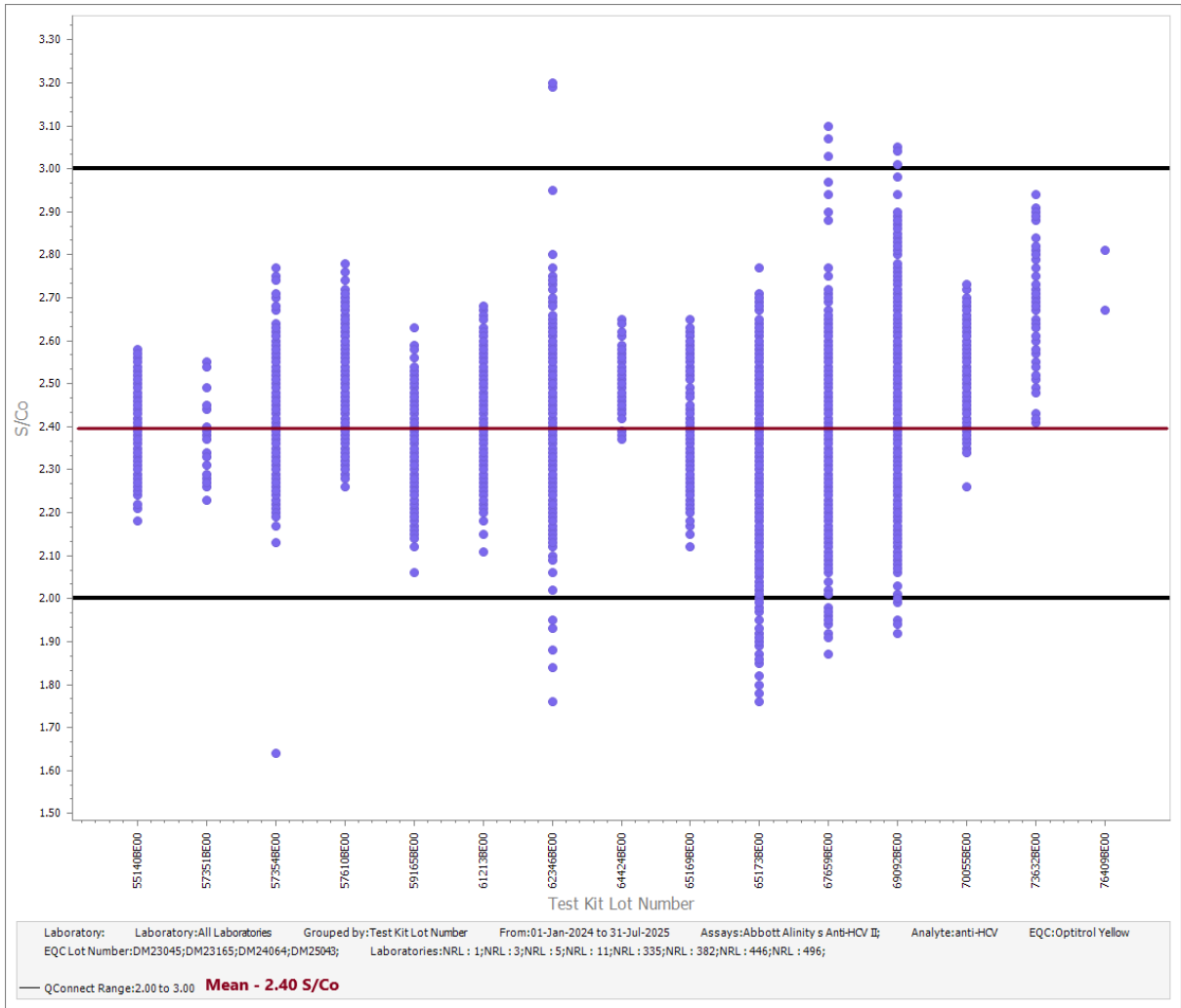


Figure 2 – Peer Group, Abbott Alinity s Anti-HCV II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.

Abbott Alinity s Anti-HTLV I/II

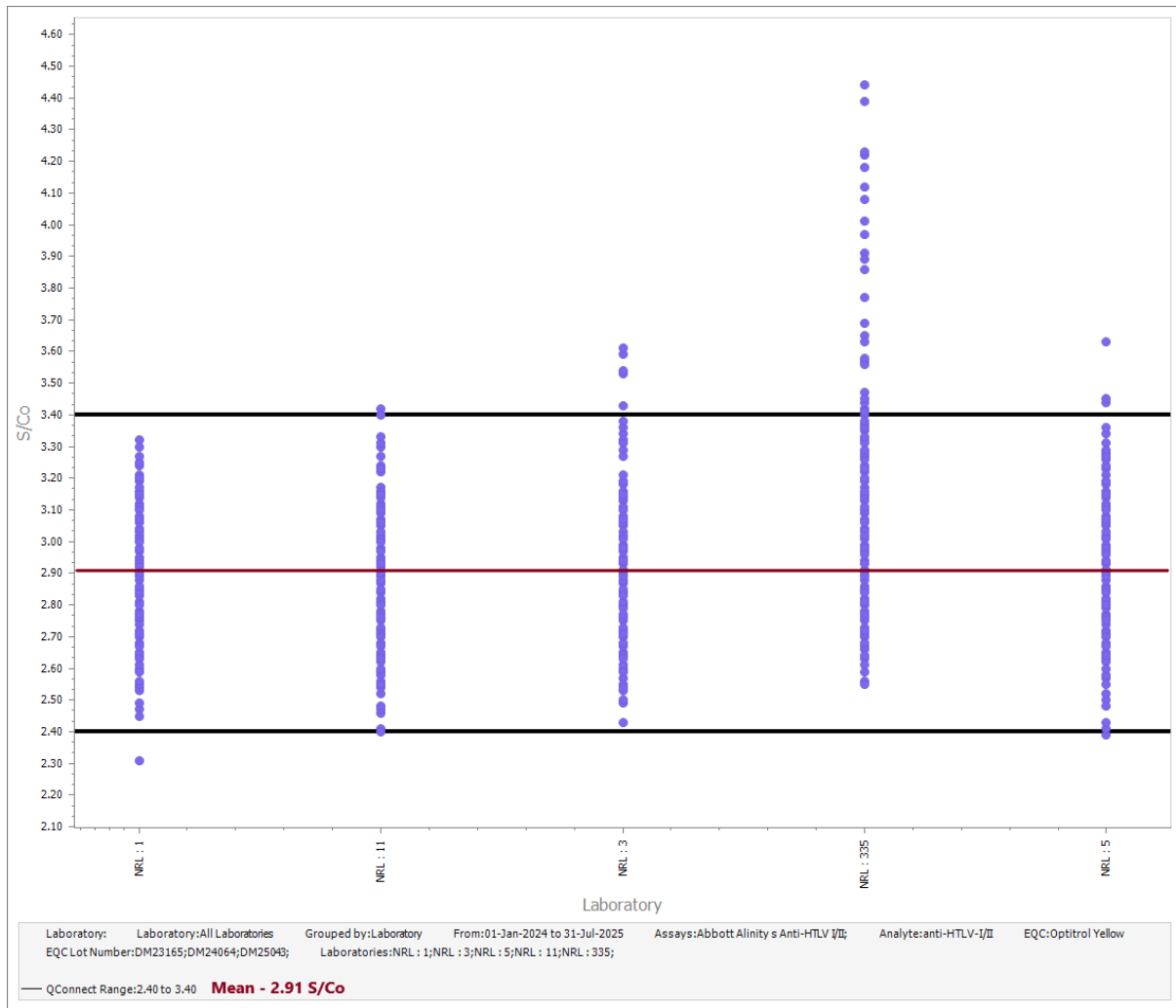


Figure 3 – Peer Group, Abbott Alinity s Anti-HTLV I/II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.

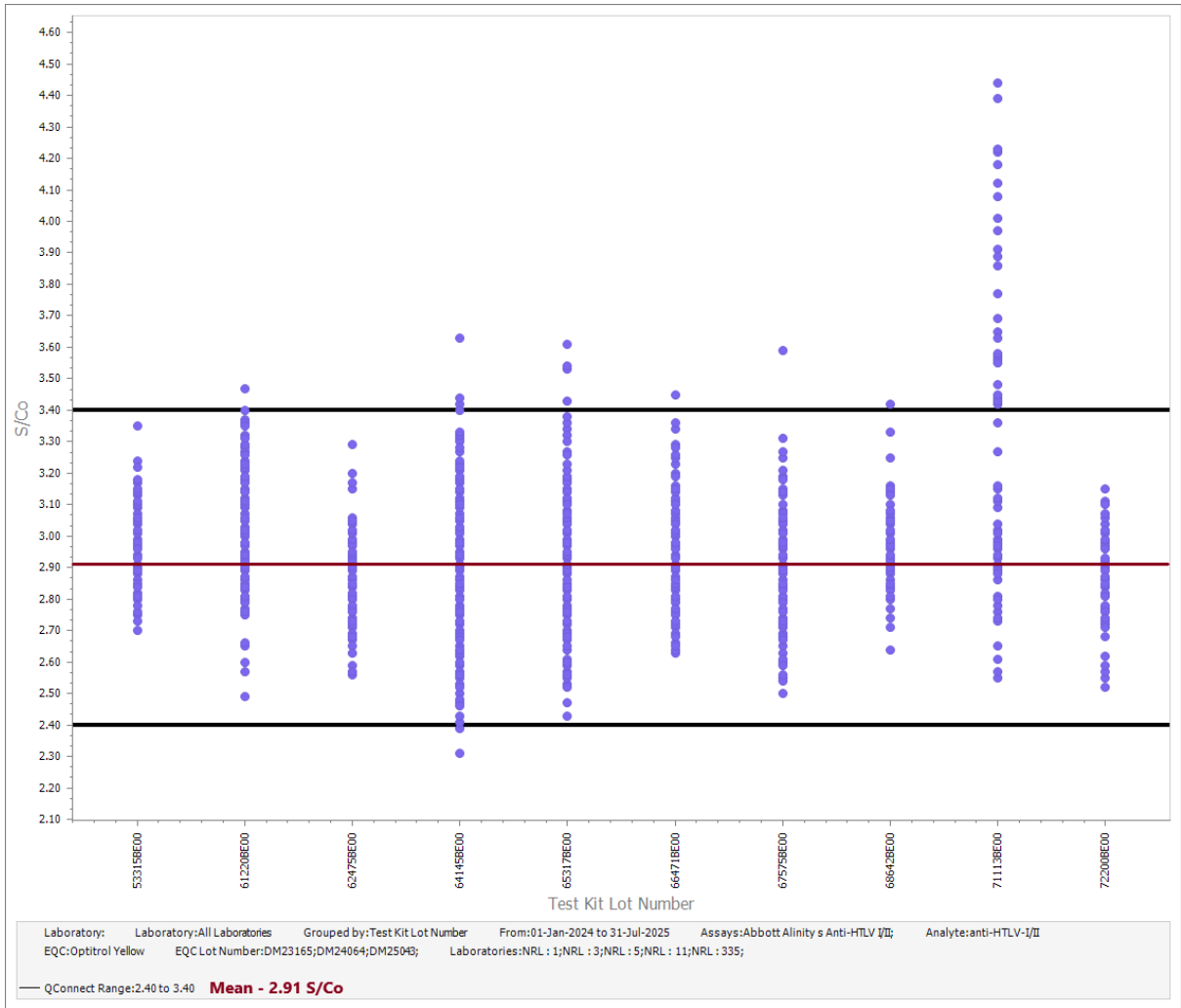


Figure 4 – Peer Group, Abbott Alinity s Anti-HTLV I/II testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.

Abbott Alinity s HBsAg

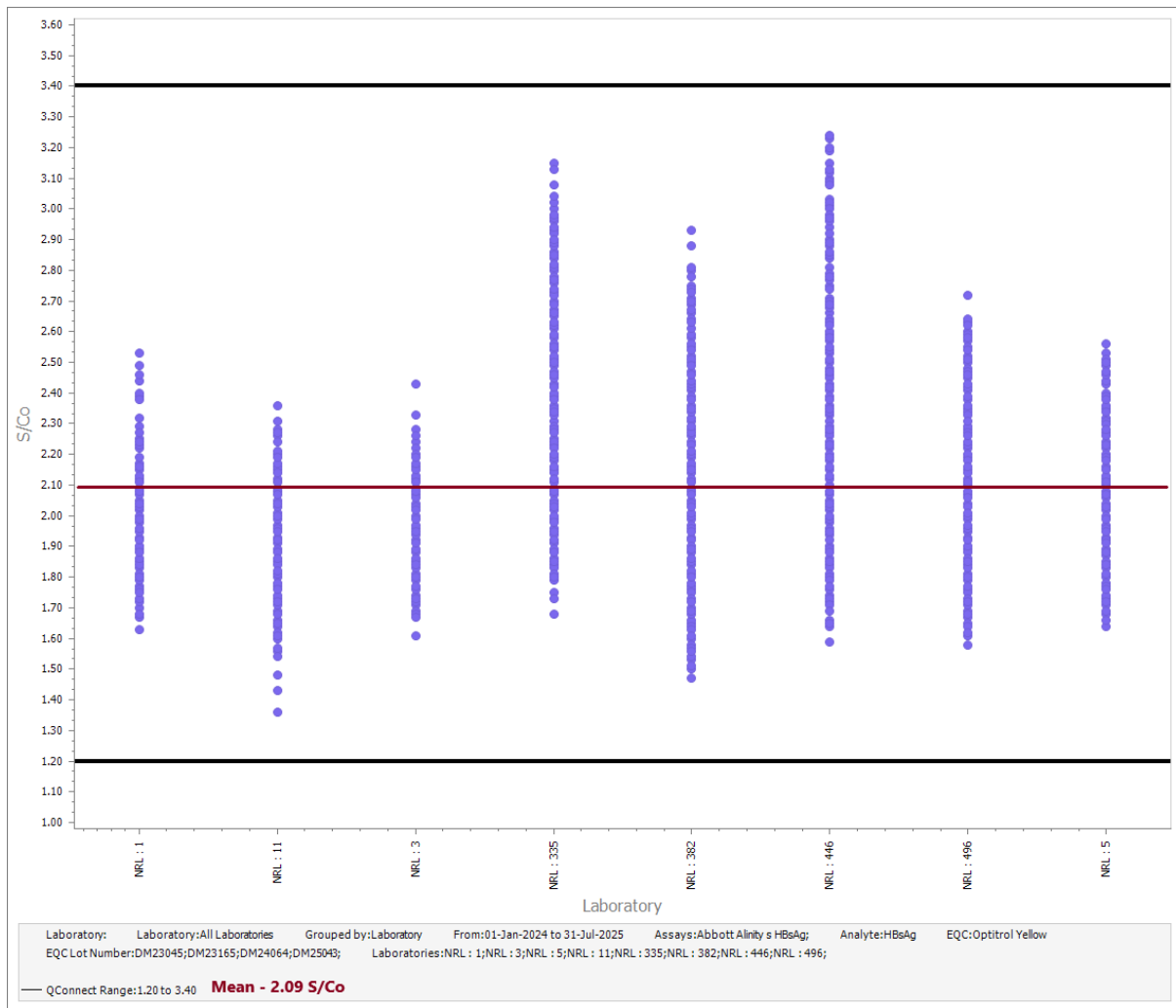


Figure 5 – Peer Group, Abbott Alinity s HBsAg testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant.

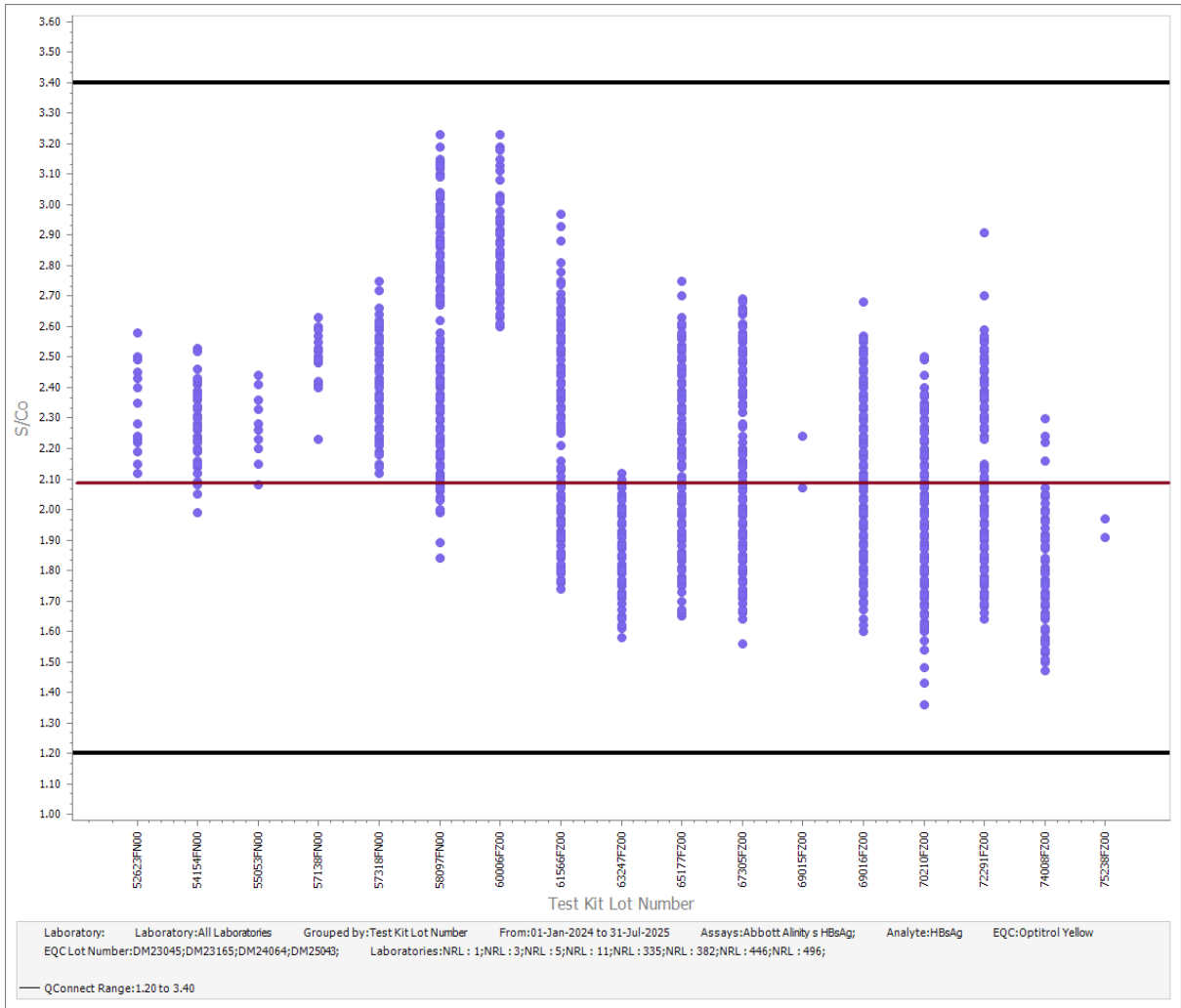


Figure 6 – Peer Group, Abbott Alinity s HBsAg testing with Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.

Abbott Alinity s HIV Ag/Ab Combo

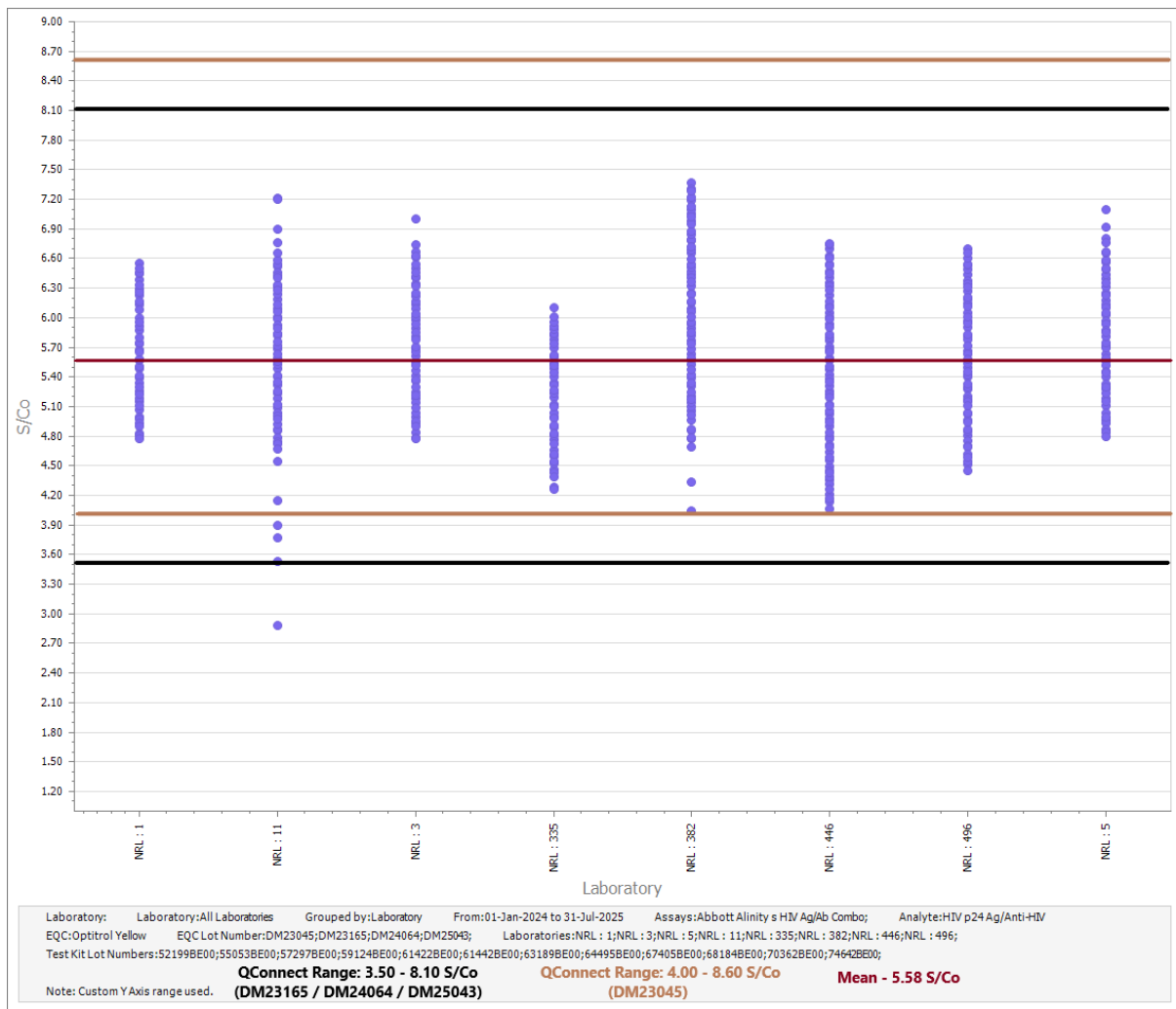


Figure 7 – Peer Group, Abbott Alinity s HIV Ab/Ag Combo testing with Optitrol Yellow Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Participant. Reagent lot numbers 71610BE00 and 73319BE00 are excluded from chart.

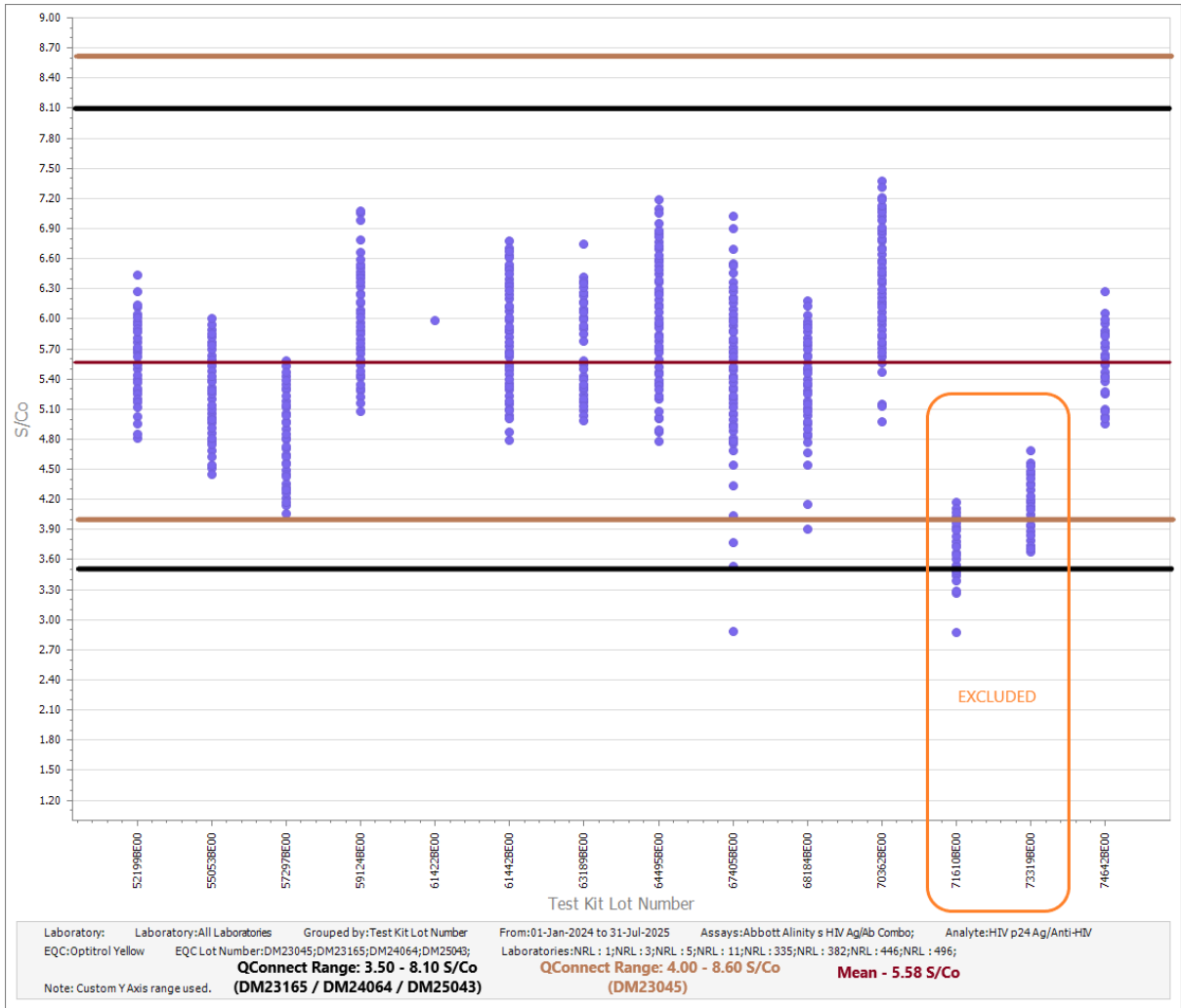


Figure 8 – Peer Group, Abbott Alinity s HIV Ab/Ag Combo testing with Optitrol Yellow Optitrol Yellow DM23045, DM23165, DM24064 and DM25043 by Reagent Lot.

Abbott Alinity s Syphilis

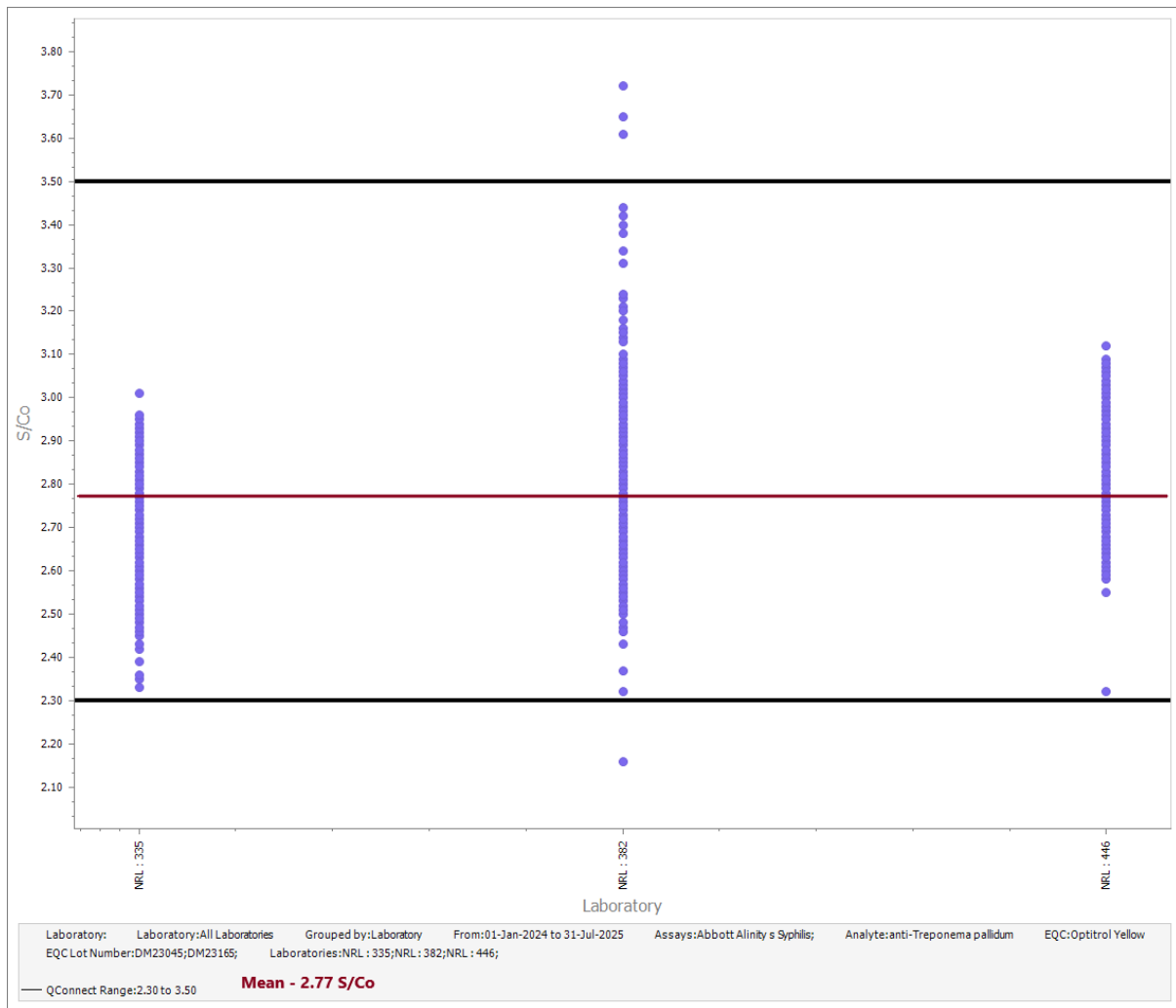


Figure 9 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM23045 and DM23165 by Participant.

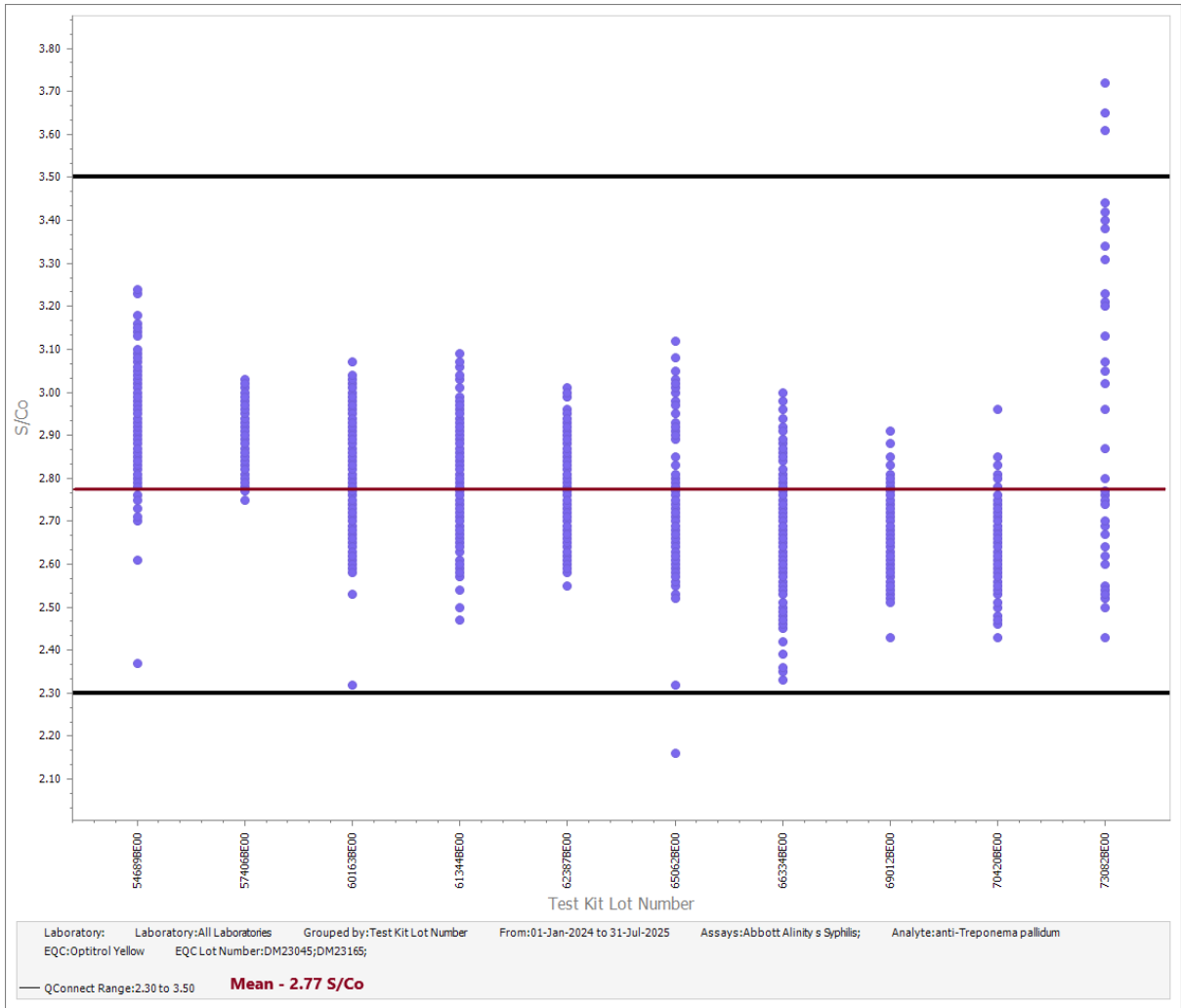


Figure 10 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM23045 and DM23165 by Reagent Lot.

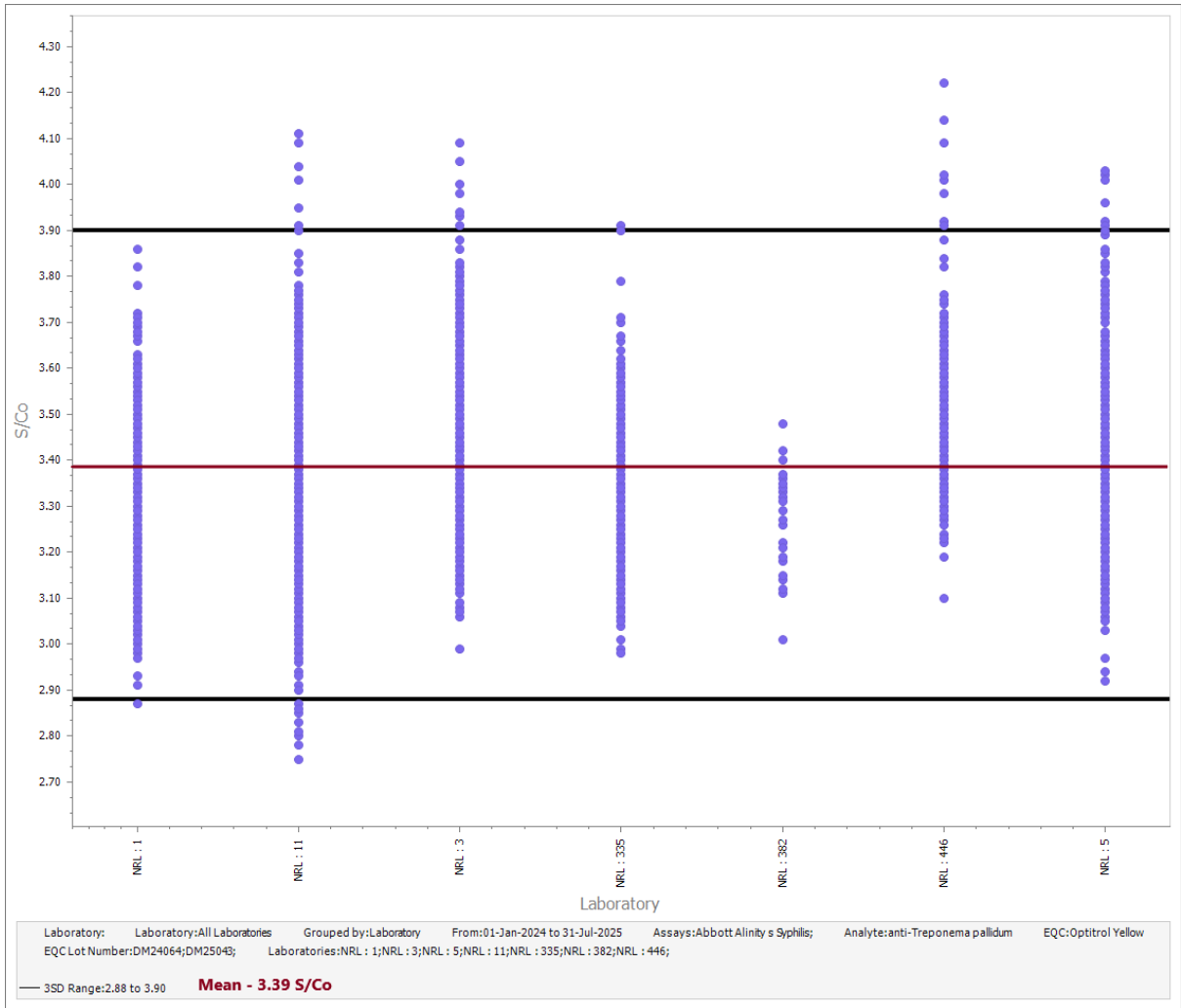


Figure 11 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM24064 and DM25043 by Participant.

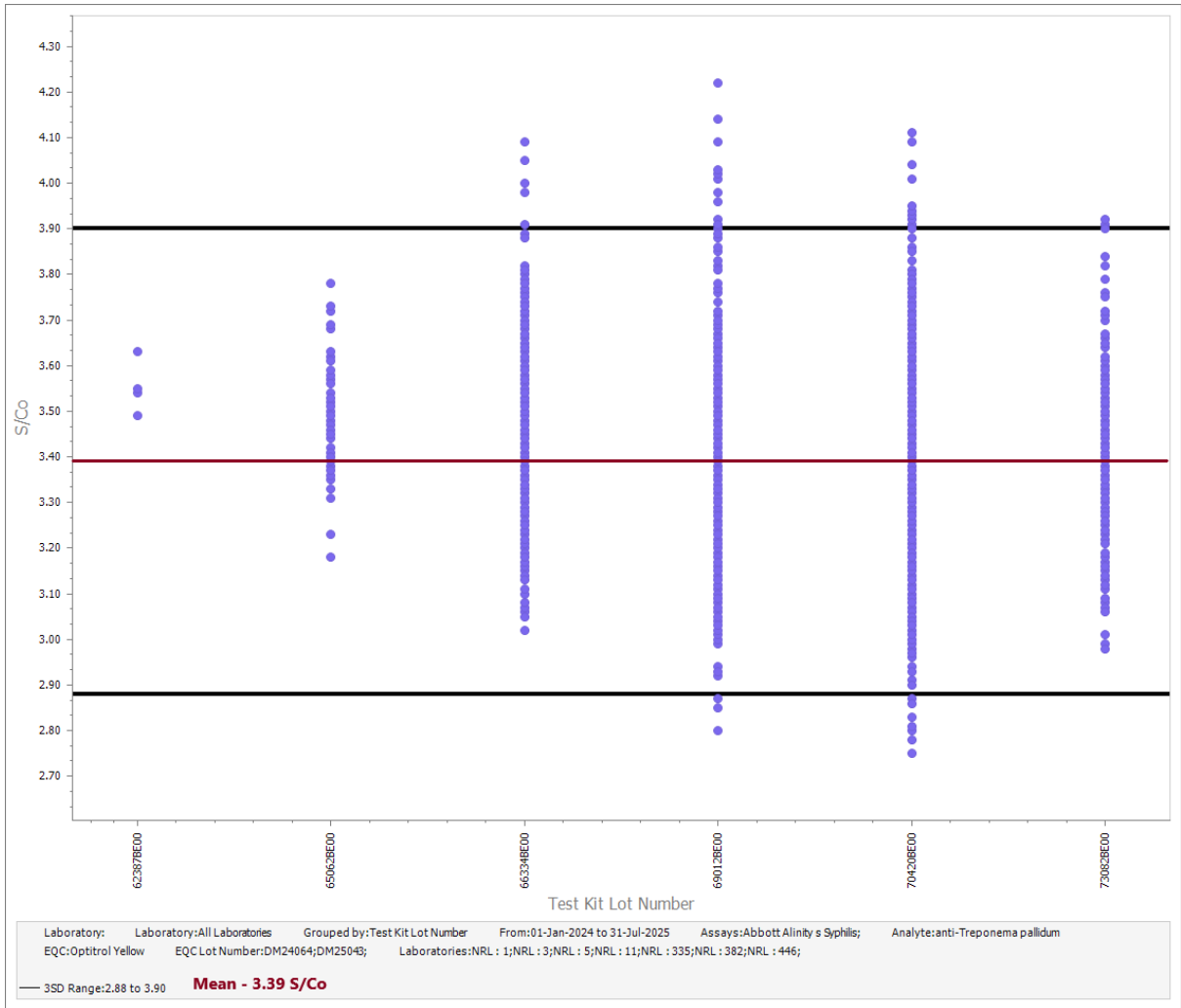


Figure 12 – Peer Group, Abbott Alinity s Syphilis testing with Optitrol Yellow DM24064 and DM25043 by Reagent Lot.