



**QC Services
Investigation:
PMM-QC-2532**

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INTRODUCTION

During routine review of data reported to EDCNet it was observed that Optitrol Blue DM24249 data were reported below the assay cut off when testing on the DiaSorin LIAISON XL MUREX HCV Ab assay. All data reported to EDCNet for Optitrol Blue DM24249 on both the DiaSorin LIAISON XL MUREX HCV Ab and other assays where Optitrol Blue is the recommended Optitrol QC product for use were reviewed to establish whether a negative shift was observed for any other peer group and identify a possible root cause.

No data for Optitrol Blue DM24249 were reported for the DiaSorin Murex anti-HCV (version 4.0) assay.

FINDINGS

- Figure 1 – Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.
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 - Figure 64 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HIV Ab/Ag HT assay for Optitrol Blue DM24249.
 - Figure 65 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX rec HTLV-I-II assay for Optitrol Blue DM24249.

DISCUSSION

Participant 1615 reported data for Optitrol Blue DM24249 on the DiaSorin LIAISON XL MUREX HCV Ab assay, illustrated in Figures 1, 2 and 3. Data for Optitrol Blue DM24249 were reported across two reagent lots: 346025 and 246026. Data for both reagent lot numbers were reported above, at and below the assay cut off (<1.00 S/Co). Figures 2 and 3 illustrate data reported by Participant 1615 for Optitrol lots (DM23117, DM23204 and DM24063) in use prior to and including DM24249. One reagent lot, 346025, had data reported for Optitrol Blue lots DM24063 and DM24249. The shift down in S/Co value observed for Optitrol Blue DM24249 was observed first for data reported for Optitrol Blue DM24063 and reagent lot 346025. No

negative data were reported for Optitrol Blue DM24063.

No DiaSorin kit control data had been submitted by Participant 1615 at the time of this report.

Participant 2247 reported data for Optitrol Blue DM24249 on the DiaSorin LIAISON XL MURE HCV Ab assay, illustrated in figures 4 through 7. Data for Optitrol Blue DM24249 were reported across two reagent lots, 346025 and 246026, only reagent lot 246026 reported data below the assay cut off. Only three data points were reported for Optitrol Blue DM24249 and reagent lot 346025. Figures five and six illustrate data reported by Participant 2247 for Optitrol lots (DM23117, DM23204 and DM24063) in use prior to and including DM24249. One reagent lot (346025) had data reported for Optitrol Blue lots DM24063 and DM24249. The shift down in S/Co value observed for data reported for DM24249 was observed first for data reported for Optitrol Blue DM24063 and reagent lot 346025. No negative data were reported for Optitrol Blue DM24063.

Participant 2247 had reported DiaSorin kit control data to EDCNet, see Figure 7. Four reagent lots: 346022, 346024, 346025 and 346026, were in use from September 2024 through to May 2025. The shift down in S/Co values observed for Optitrol Blue were also observed for data reported for the DiaSorin Positive Kit control for reagent lots 346025 and 346026. No negative data were reported for the DiaSorin Positive Kit Control.

Figures 8 and 9 illustrate DiaSorin LIAISON XL MUREX HCV Ab assay peer group data for Optitrol Blue DM24249 by participant and reagent lot, respectively. Data were consistent across the peer group with examples of data reported below the assay cut off (<1.00 S/Co) for both participants.

Figures 10 and 11 illustrate DiaSorin LIAISON XL MUREX HCV Ab assay peer group data for Optitrol Blue lots (DM23117, DM23204 and DM24063) in use prior to DM24249 by participant and reagent lot. Respectively. Data were consistent across the peer group and no data were reported below the assay cut off (<1.00 S/Co).

Figures 12 and 13 illustrate DiaSorin LIAISON XL MUREX HCV Ab assay peer group data for Optitrol Blue lots (DM23117, DM23204 and DM24063) in use prior to and including DM24249 by participant and reagent lot, respectively. Data were reported below the assay cut off for Participants 1615 and 2247.

Figures 14 and 15 illustrate DiaSorin LIAISON XL MUREX HCV Ab assay peer group data for available DiaSorin positive kit control data. Data were available for four participants across nine reagent lots. A similar shift down in S/Co value for reagent lots 346025 and 346026 was also observed for data reported for the assay positive control.

Figures 16 through 24 show individual peer group data for DiaSorin LIAISON XL MUREX HCV Ab assay peer group participants reporting data for Optitrol Blue lots DM23117, DM23204 and DM24063 and assay positive control. All but one participant (Participant 1853) reported assay positive control data to EDCNet.

Similar reagent lot variation was observed across the peer group for both Optitrol Blue and assay positive control data reported for reagent lots 346025 and 346026. One participant (1356) showed a shift up and an increase in variation for data reported for reagent lots 346024, 346025 and 346026. This variation is the subject of a separate investigation (PMM-QC-2558).

A total of seven participants, including Participants 1615 and 2247, had reported Optitrol Blue

data for reagent lots 346025 and 346026 on the DiaSorin LIAISON XL MUREX HCV Ab assay. Four of these seven participants had reported data for both reagent lots. All of these participants showed a similar shift down in S/Co value for data reported for both Optitrol Blue lots and assay positive control.

Figures 25 through 48 show individual peer group data for Optitrol Blue DM24249 reported on the Abbott Alinity I Anti-HCV I assay. No unexpected shift or negative data were observed.

Figures 49 through 55 show individual peer group data for Optitrol Blue DM24249 reported on the Abbott ARCHITECT Anti-HCV II assay. No unexpected shift or negative data were observed.

Figures 56 through 65 show individual participant data reported for Optitrol Blue DM24249 for all other DiaSorin LIAISON assays, including DiaSorin LIAISON Treponema Screen, DiaSorin LIAISON XL MUREX HBsAg Quant, DiaSorin LIAISON XL MUREX HIV Ab/Ag, DiaSorin LIAISON XL MUREX HIV Ab/Ag HT and DiaSorin LIAISON XL MUREX rec HTLV-I-II, where Optitrol Blue is recommended for use. No unexpected shift or negative data were observed.

NRL received communication from DiaSorin Australia Pty Ltd confirming pre-release testing of reagent lots 346025 and 346026 had shown no fluctuation across the different reagent lots, and no manufacturing change had been made prior to or during manufacture.

NRL received communication from DiaMex confirming a new negative stock material was in use for the production for Optitrol Blue DM24249. No dilution factors were changed, and release testing results were consistent with previous Optitrol Blue lots.

RECOMMENDATIONS

NRL to work with DiaMex to review validation testing of new negative plasma stock material.

NRL to work with DiaMex to review dilution factors of each analyte in Optitrol Blue DM24249.

NRL request 'base' stock material parallel testing with Optitrol Blue DM24249.

NRL requests DiaMex to provide reagent details used in Lot release testing of Optitrol Blue DM24249.

NRL to work with DiaSorin to investigate further possible sources of variation, calibrators or LIAISON stock material.

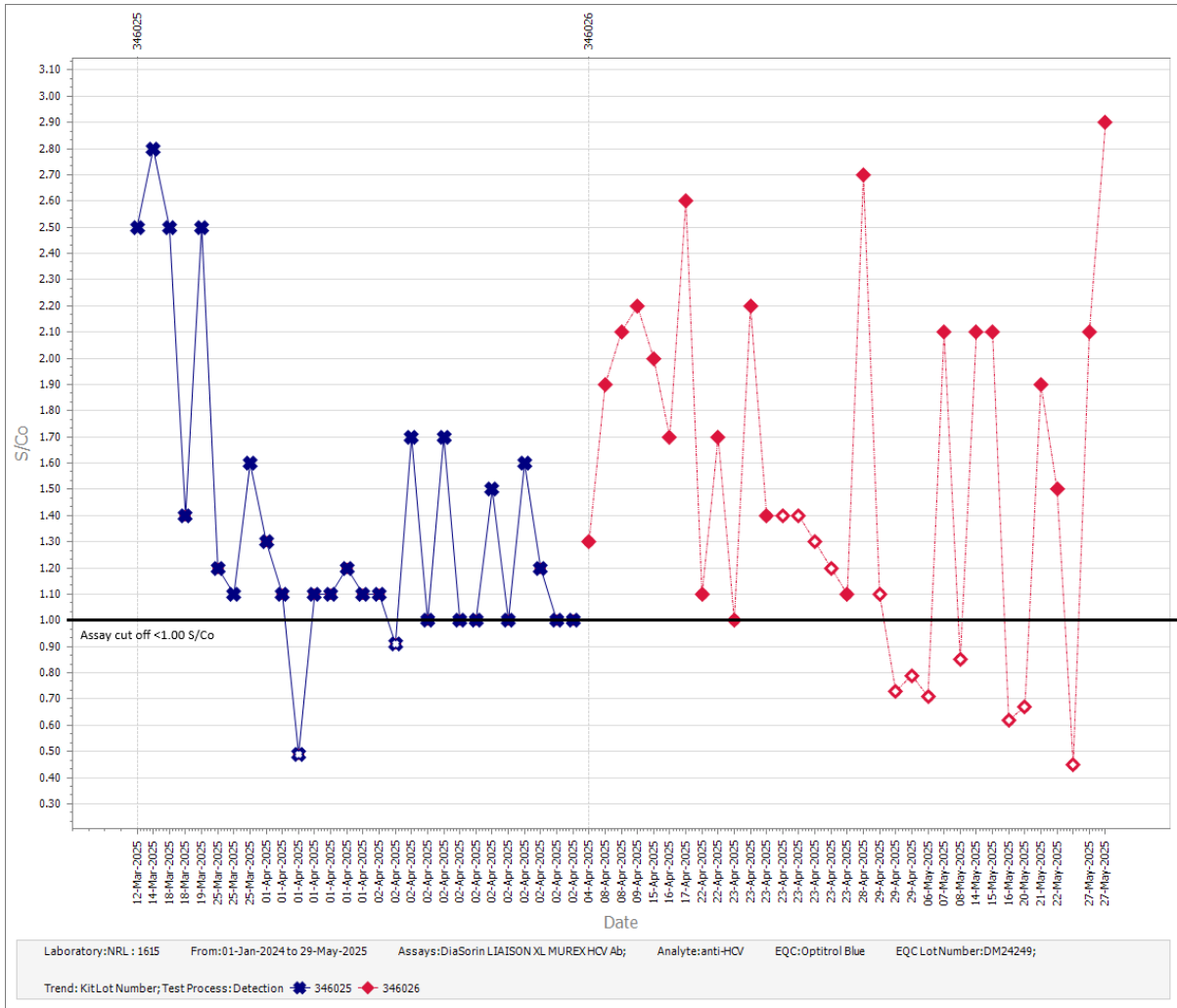


Figure 1 – Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.

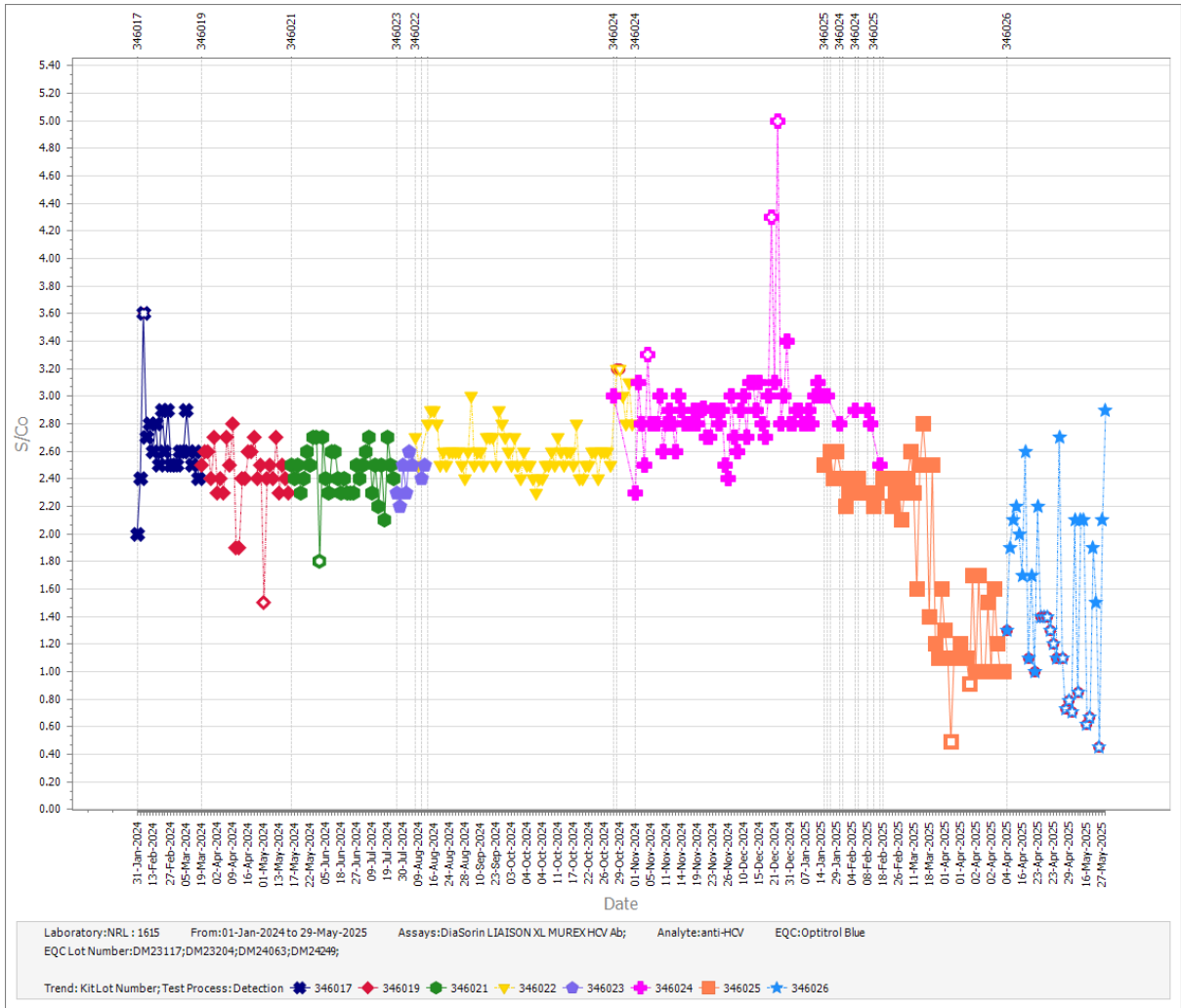


Figure 2 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue lots, DM23117, DM23204, DM24063 and DM24249.

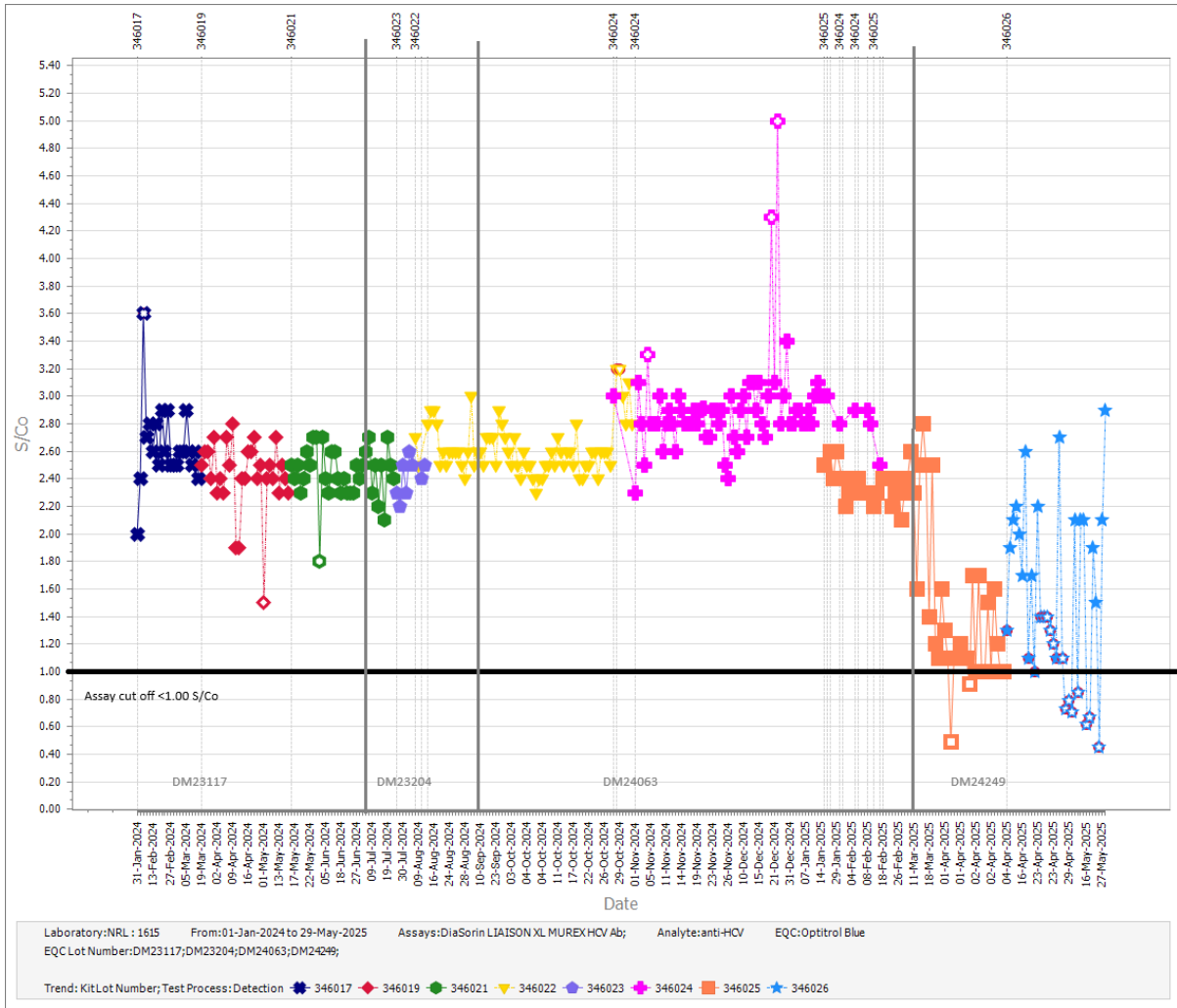


Figure 3 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue lots, DM23117, DM23204, DM24063 and DM24249 illustrating change of each Optitrol Blue lot.

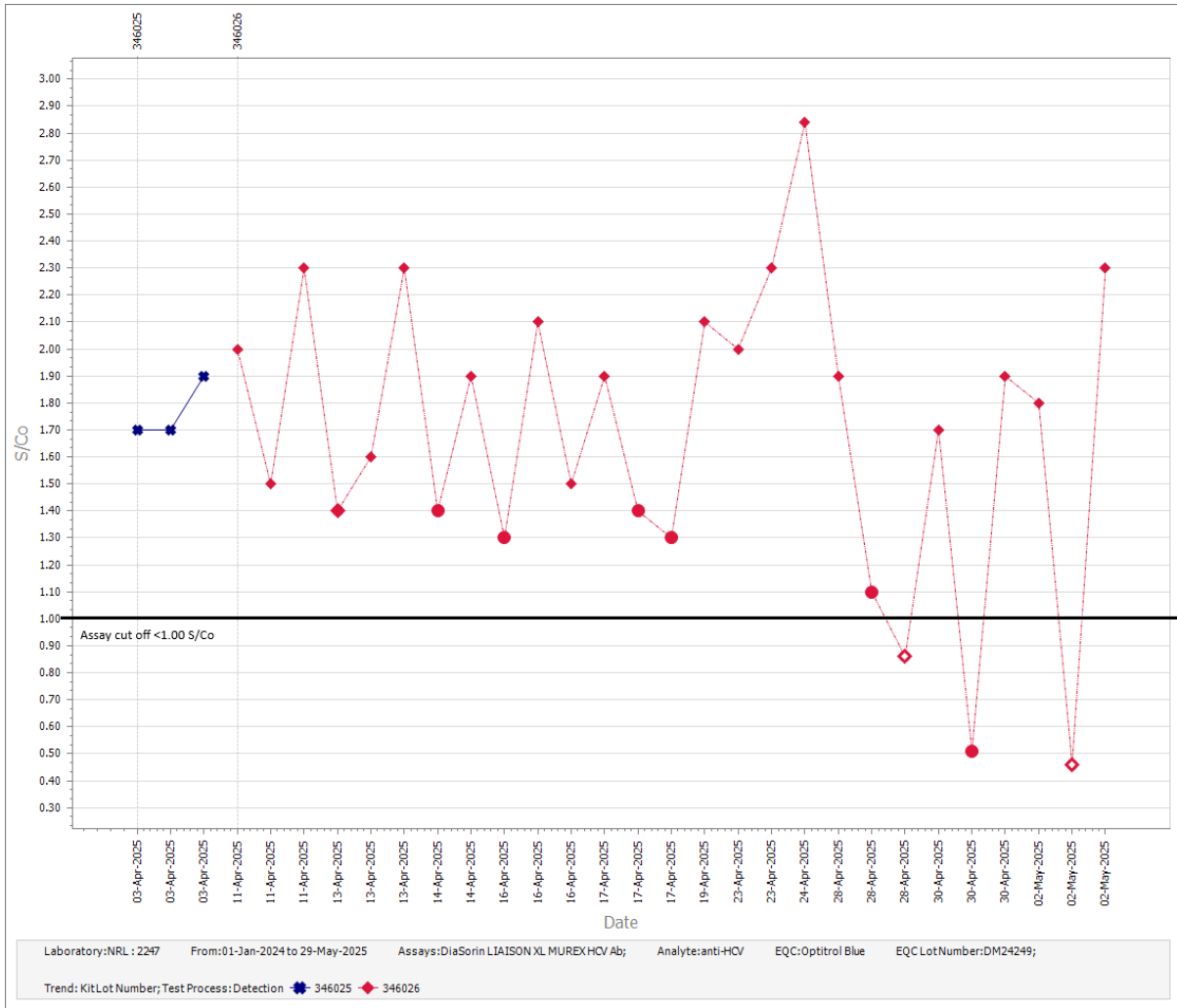


Figure 4 – Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.

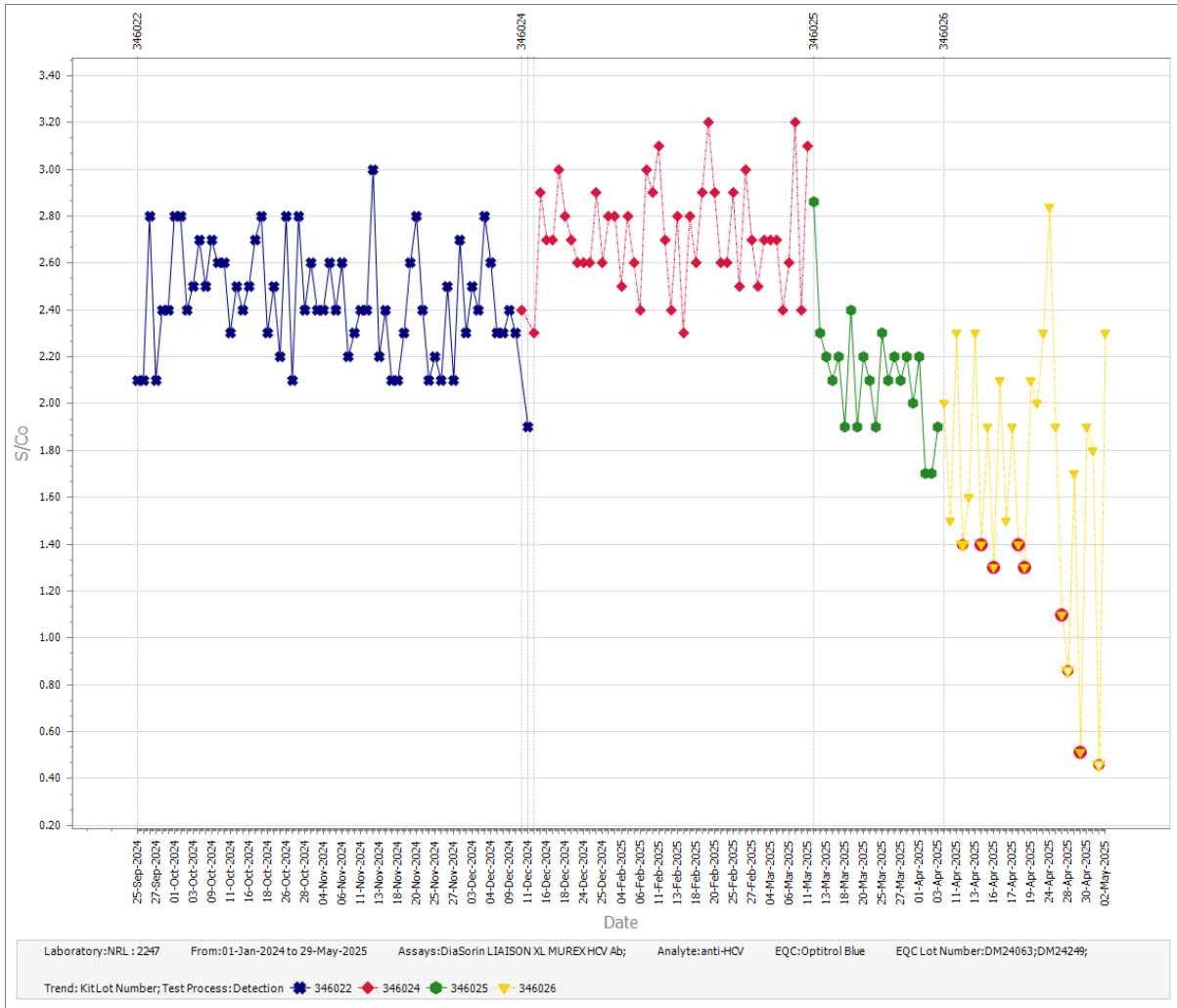


Figure 5 - Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue lots, DM23117, DM23204, DM24063 and DM24249.

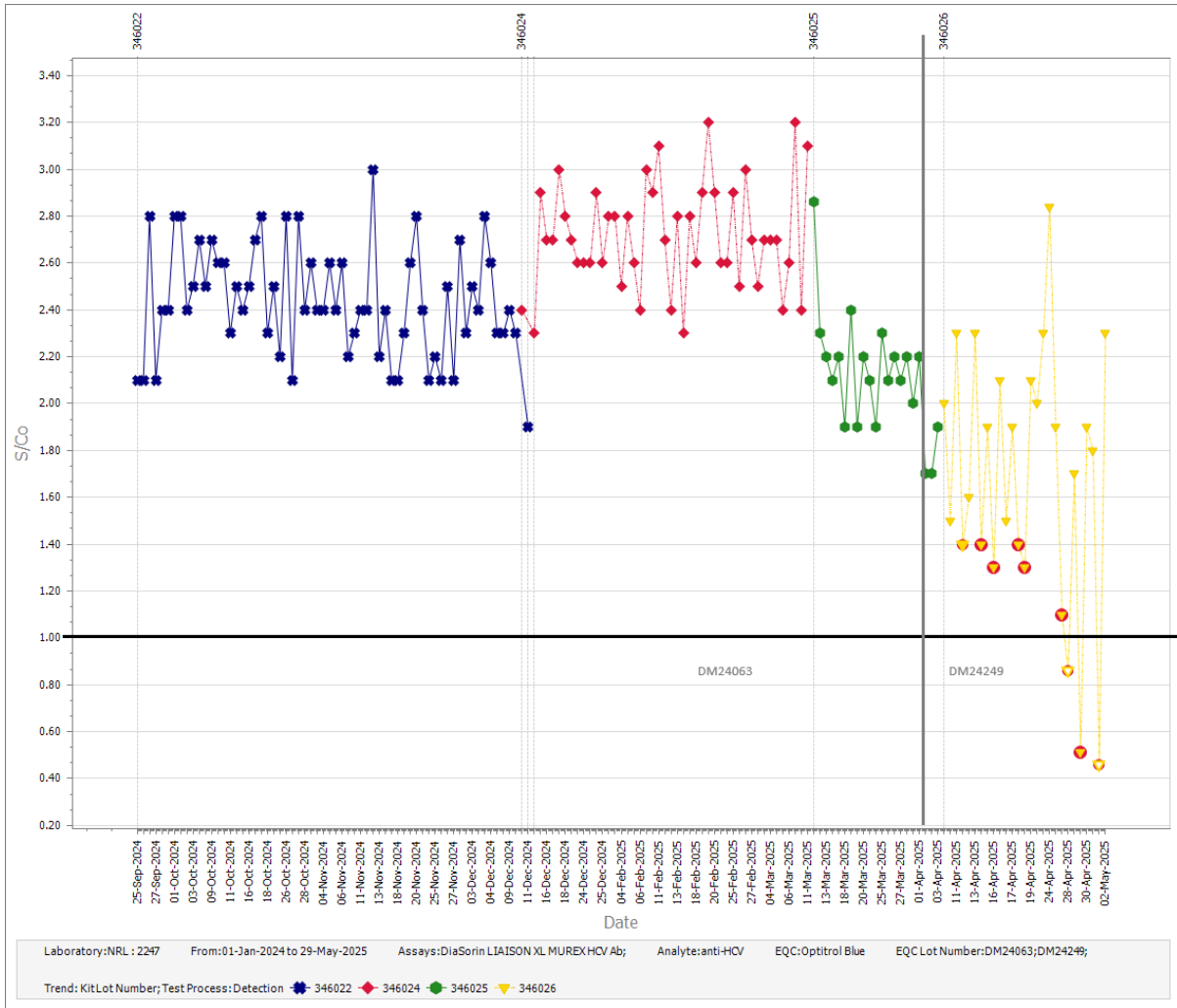


Figure 6 - Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue lots, DM23117, DM23204, DM24063 and DM24249. Illustrating usage of each Optitrol Blue lot.

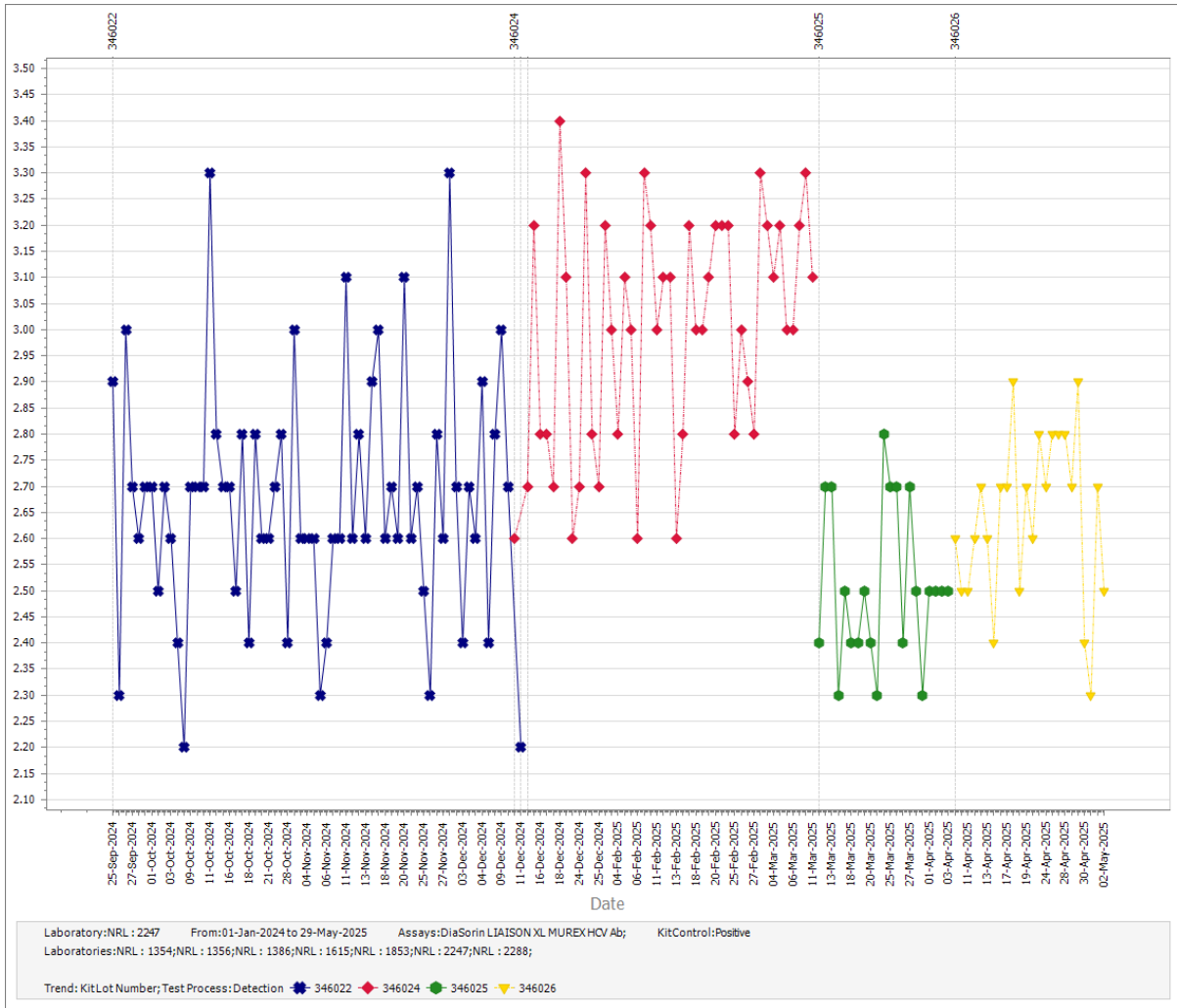


Figure 7 - Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for the DiaSorin Positive Kit Control.

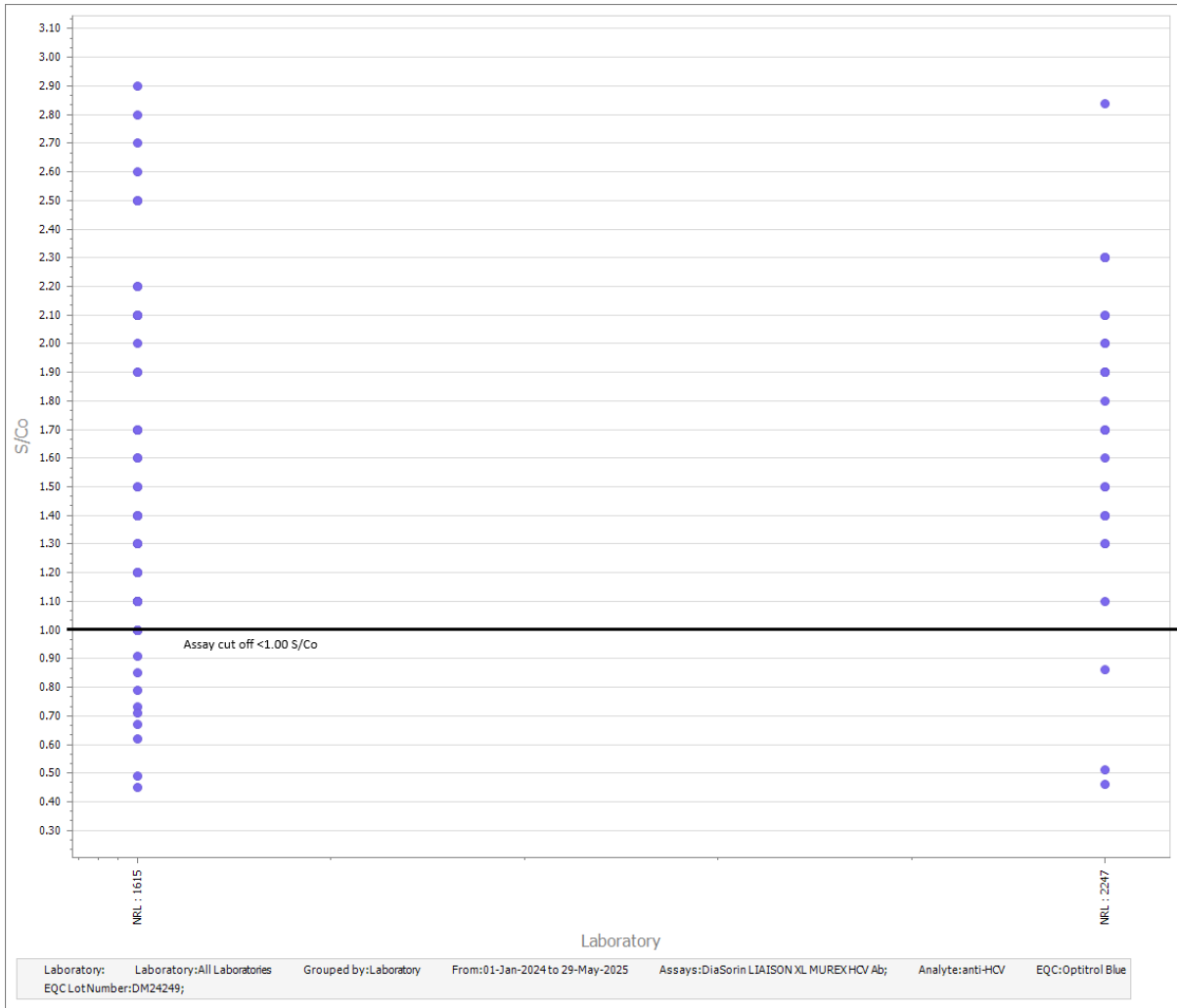


Figure 8- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue DM24249 by Participant.

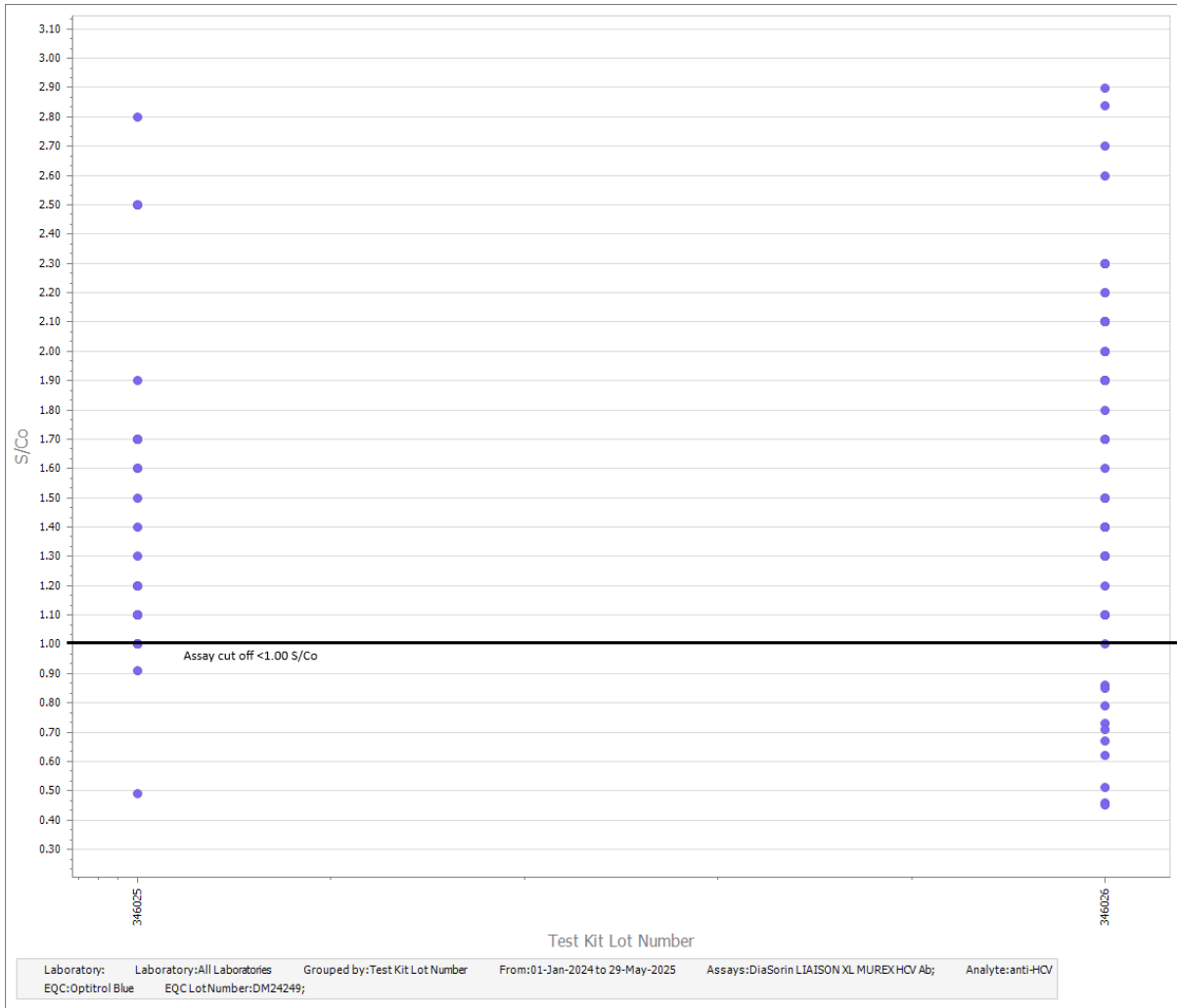


Figure 9- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue DM24249 by reagent lot.

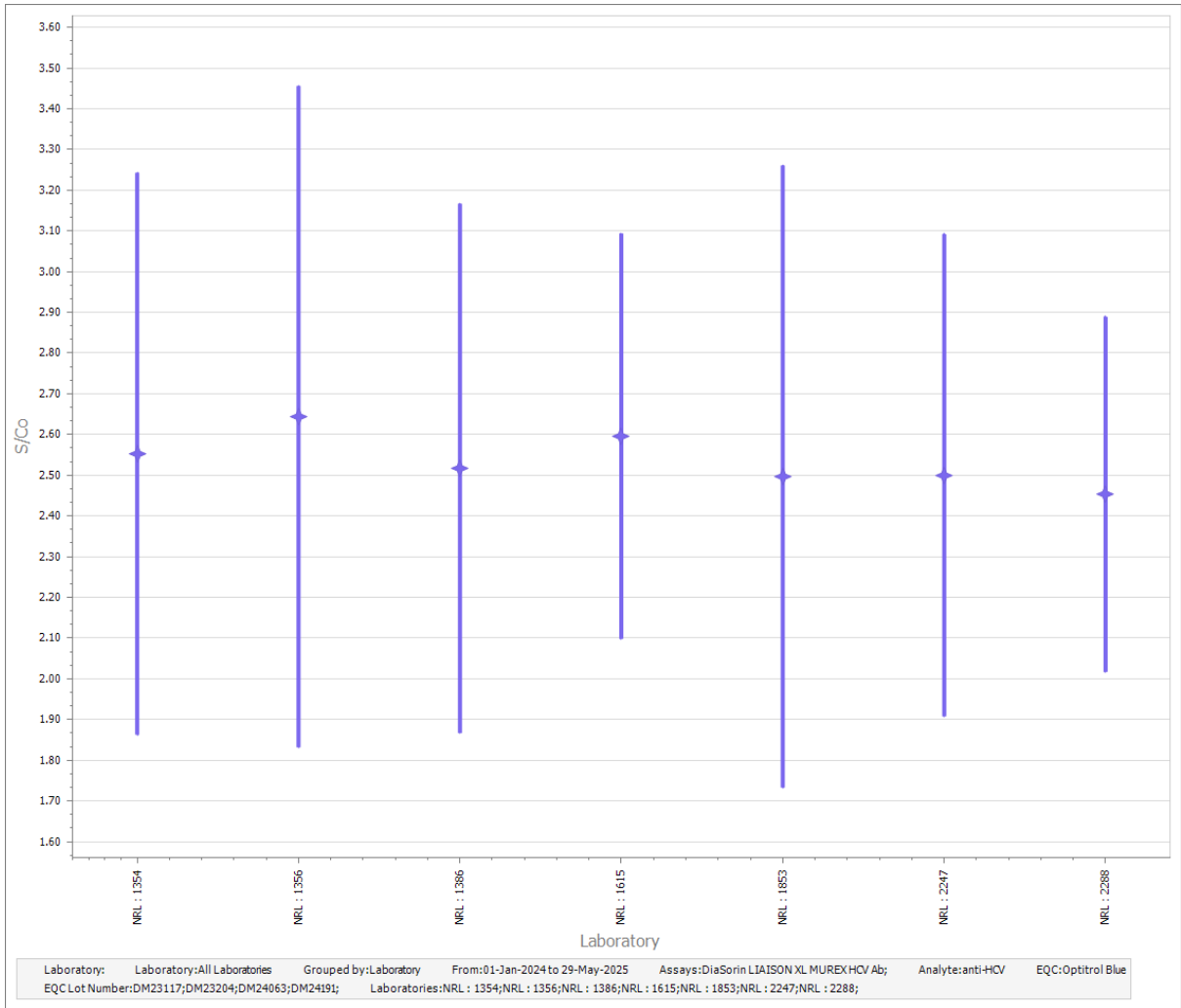


Figure 10- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue lots DM23117, DM23204 and DM24063 by Participant.

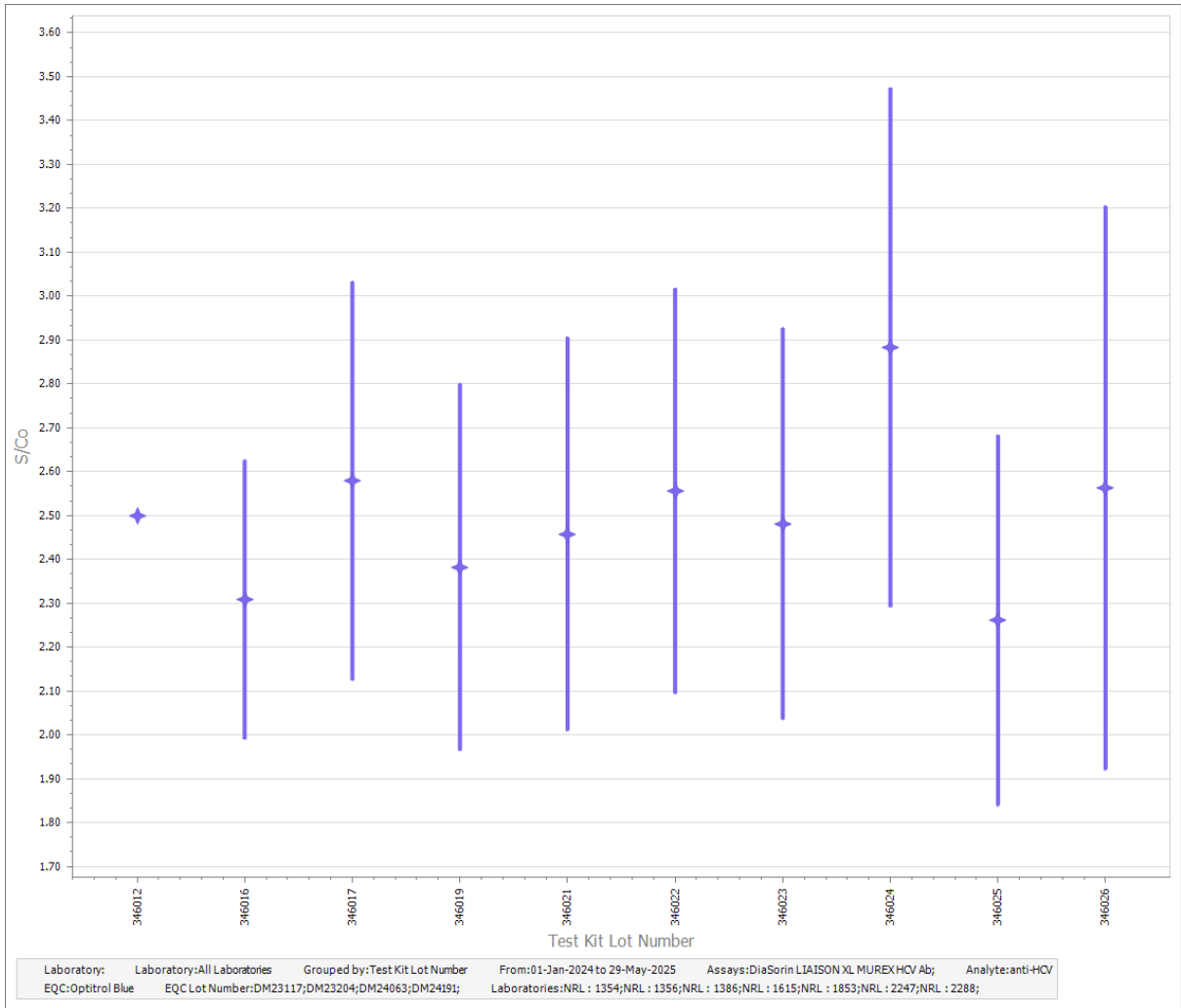


Figure 11- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue lots DM23117, DM23204 and DM24063 by reagent lot.

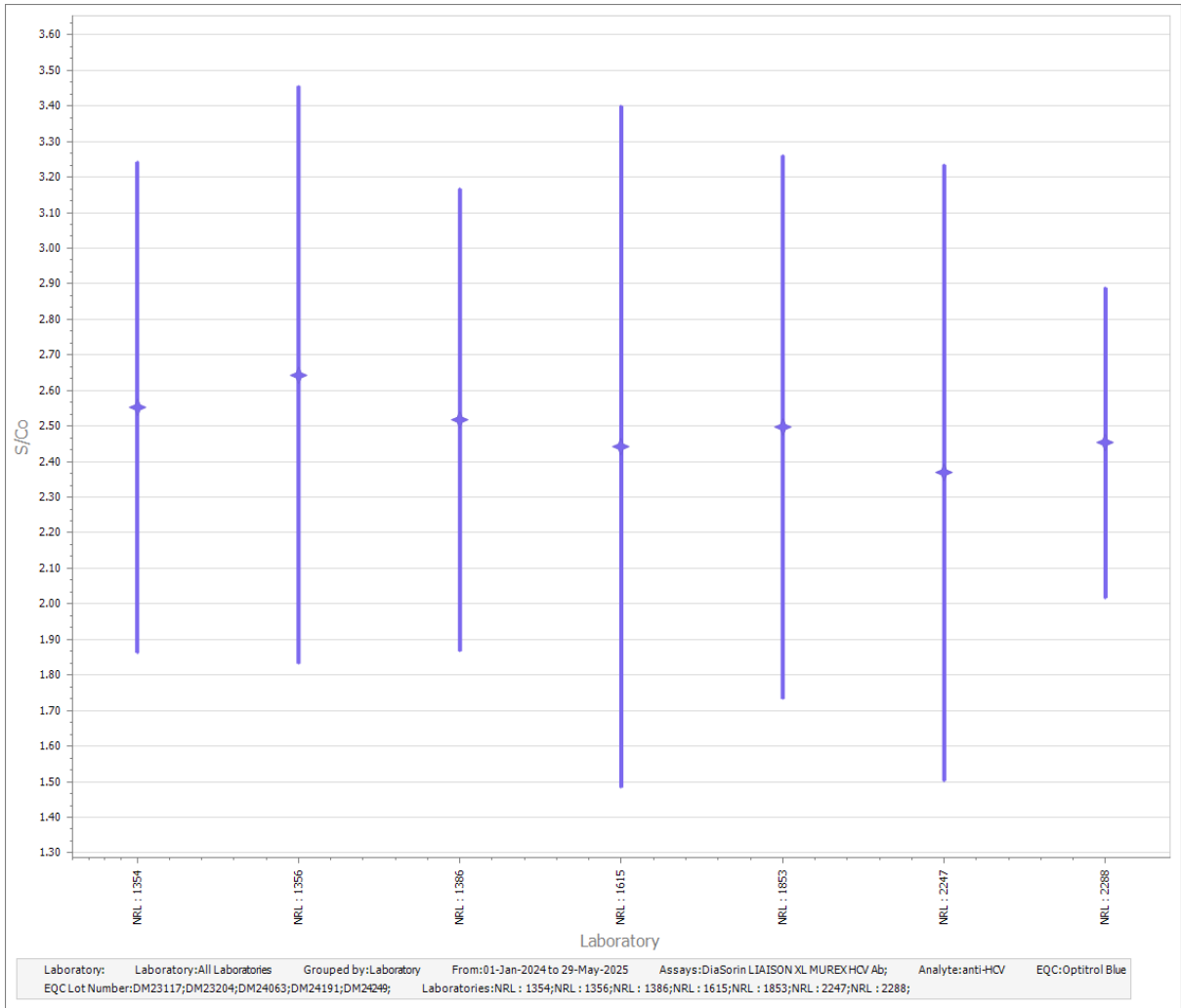


Figure 12- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue lots DM23117, DM23204, DM24063 and DM24249 by Participant.

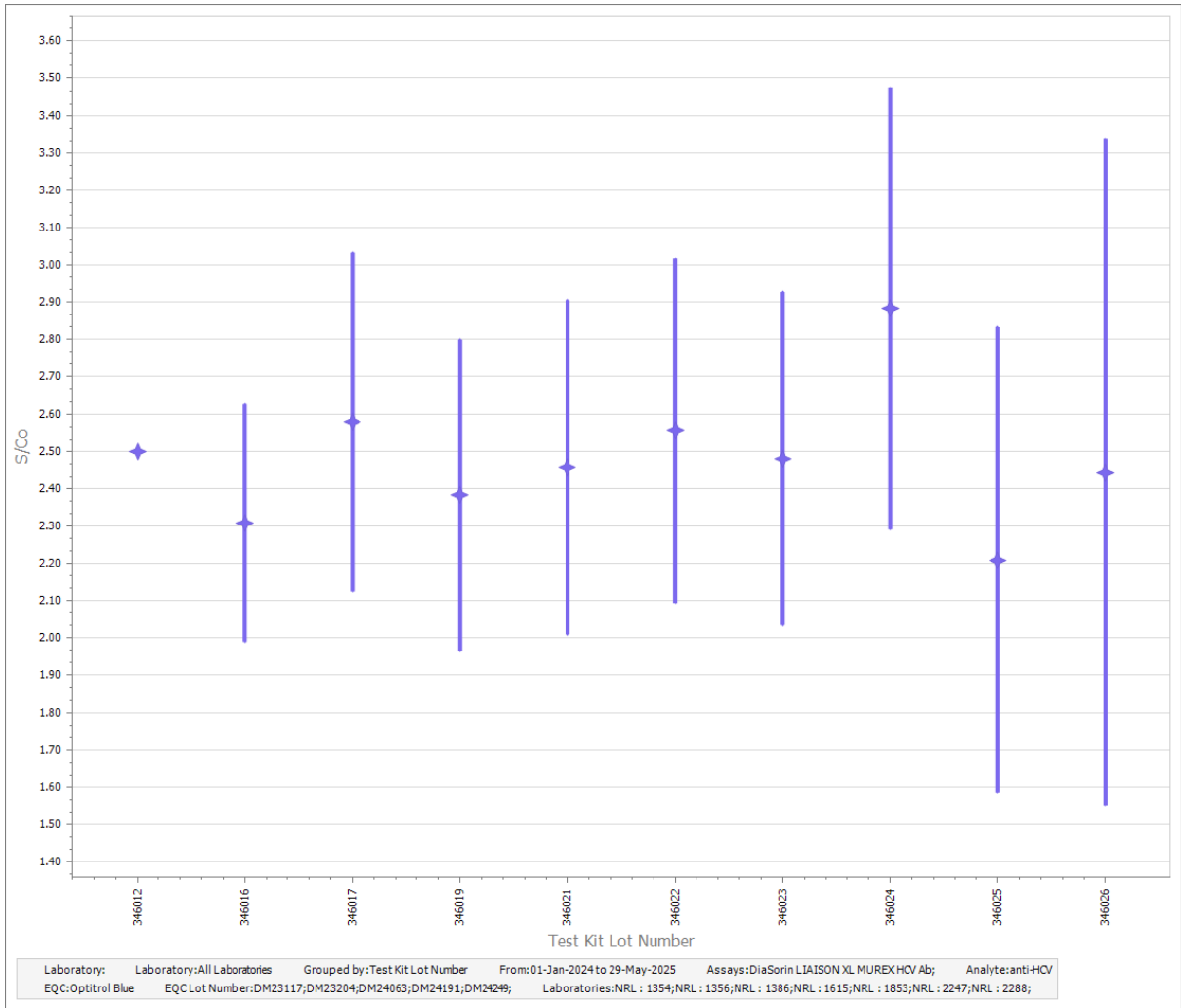


Figure 13- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for Optitrol Blue lots DM23117, DM23204, DM24063 and DM24249 by reagent lot.

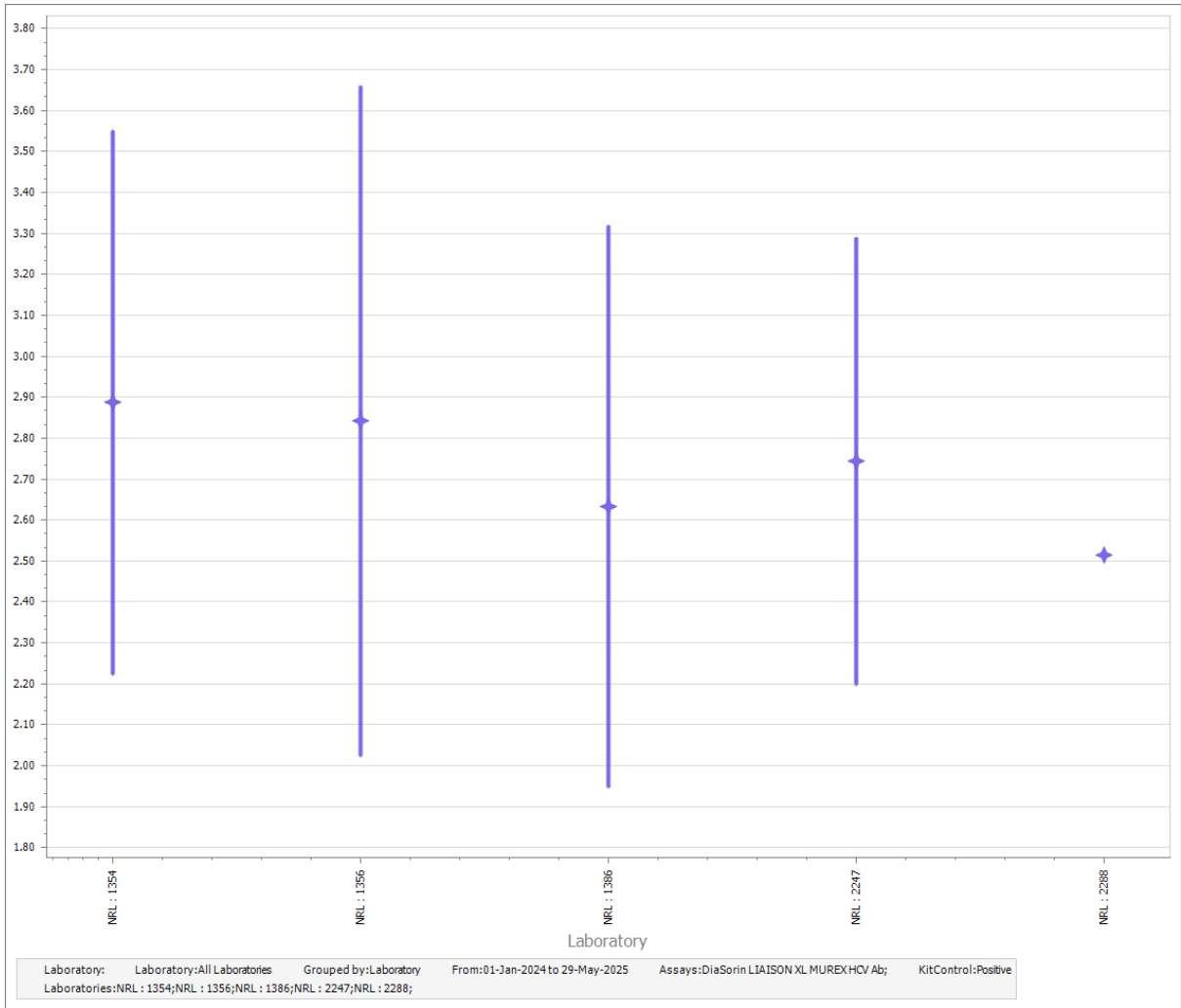


Figure 14- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for DiaSorin Positive Kit Control data by Participant.

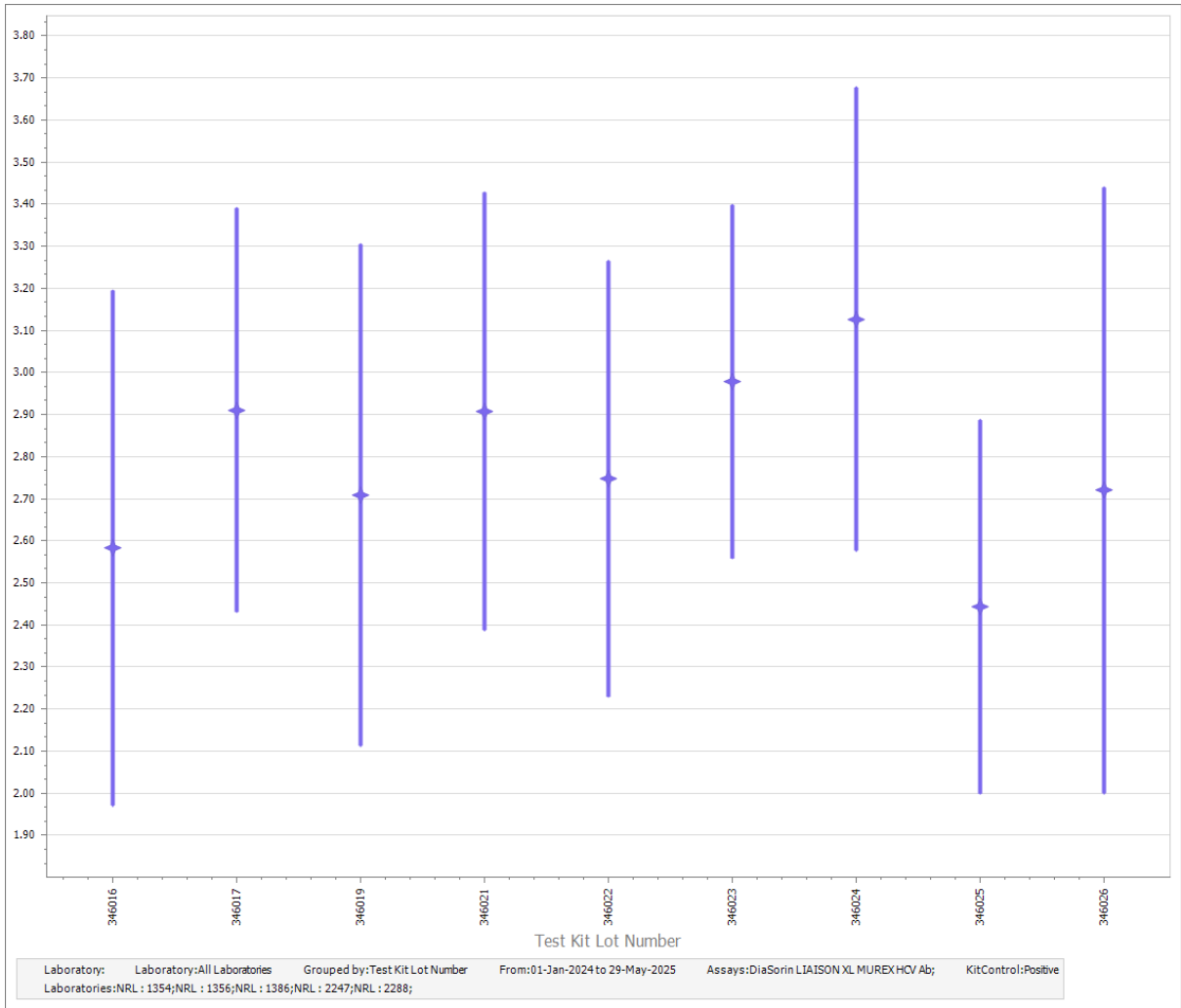


Figure 15- Peer Group data reported for the DiaSorin LIAISON XL Murex HCV Ab assay for DiaSorin Positive Kit Control data by reagent lot.

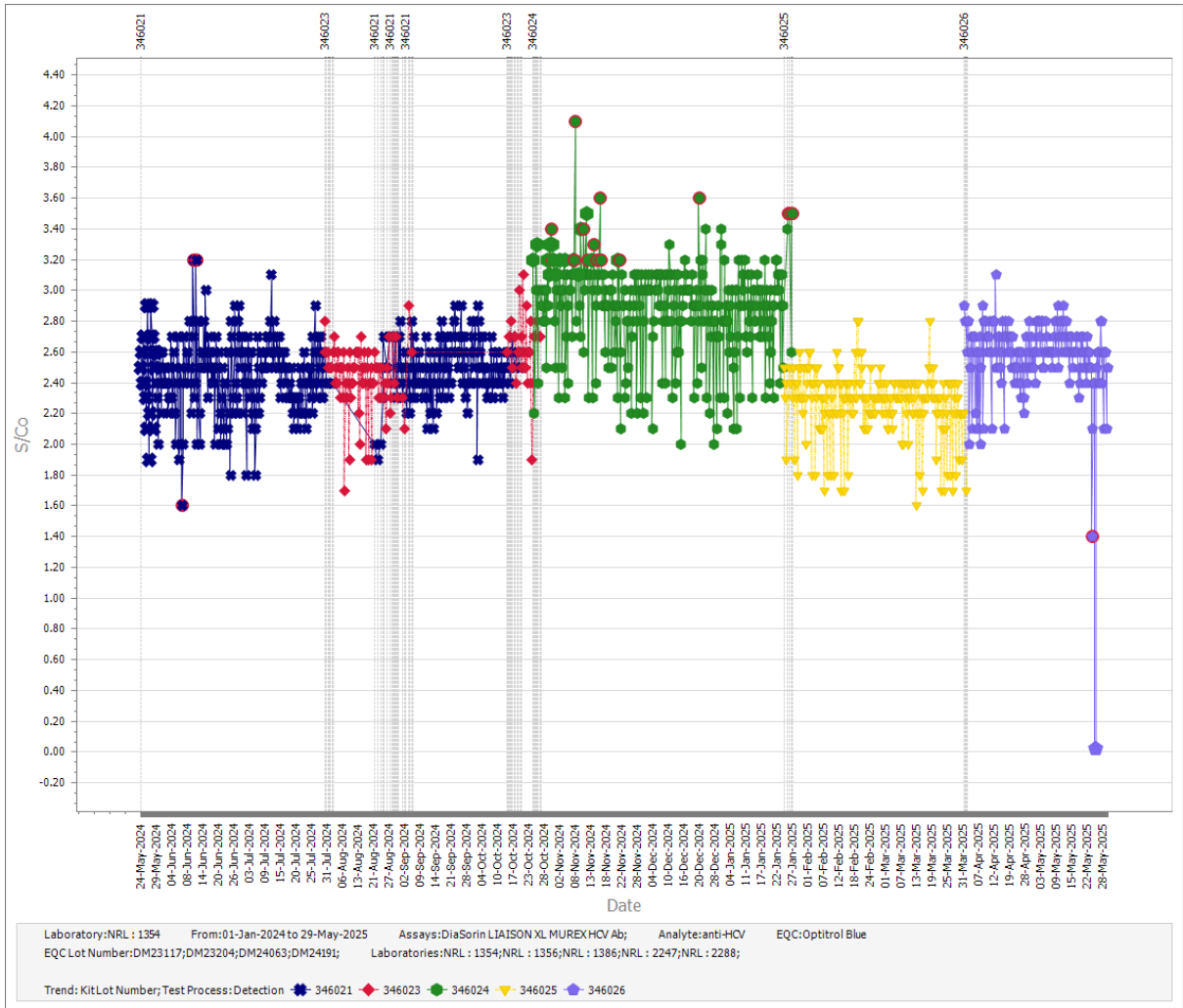


Figure 16- Participant 1354 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue lots previous to DM24249.

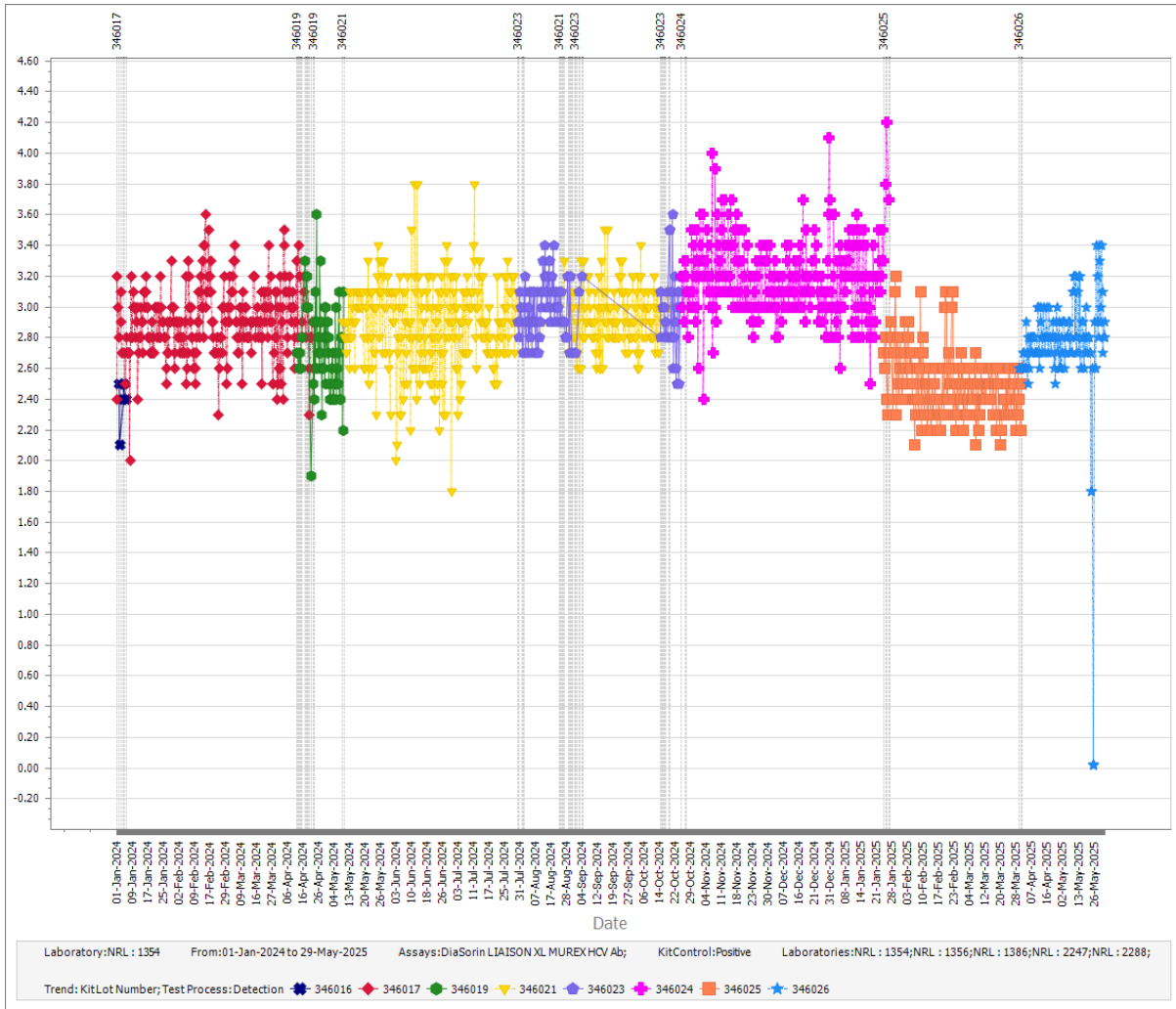


Figure 17- Participant 1354 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for DiaSorin Positive Kit Control.

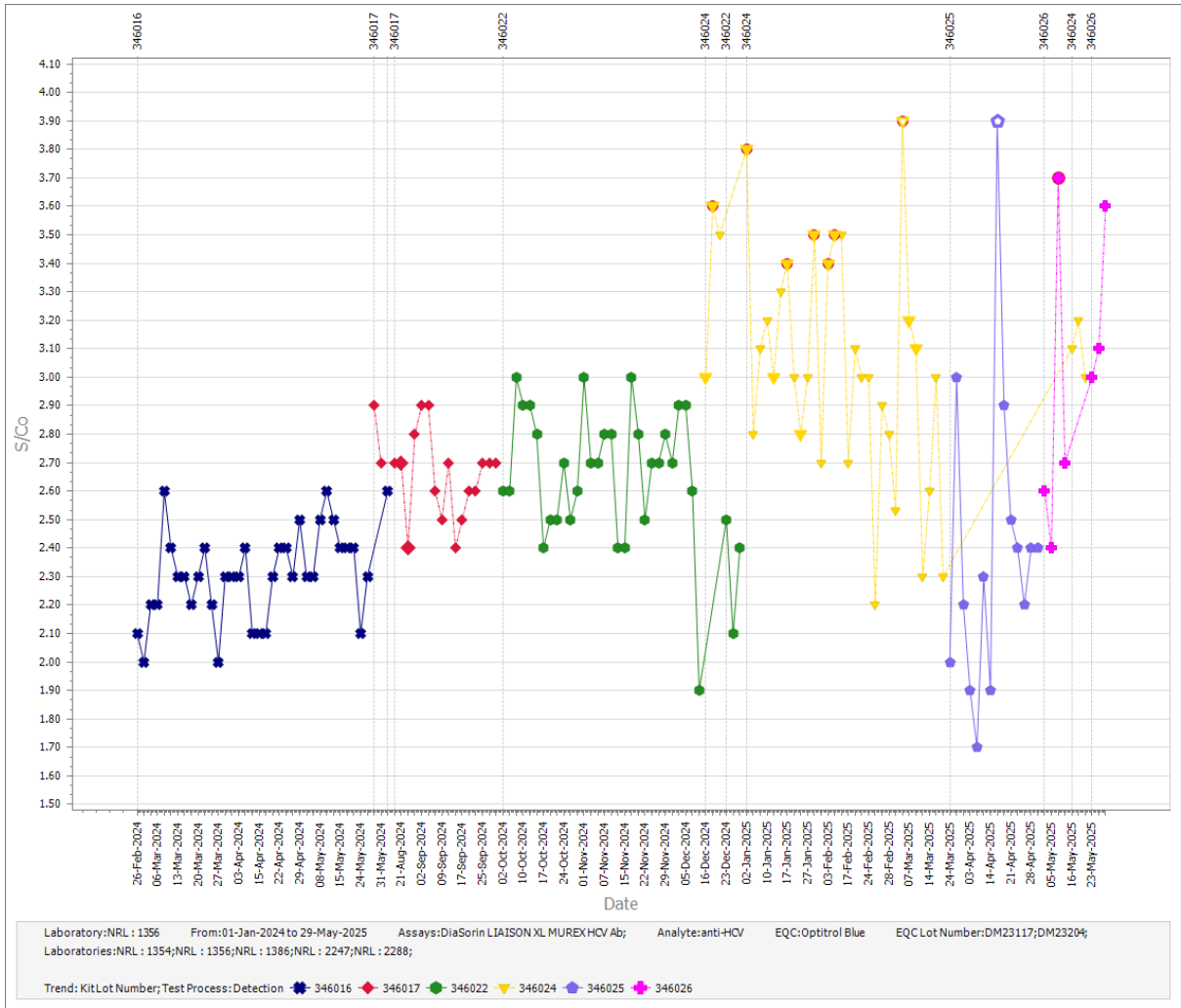


Figure 18- Participant 1356 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.

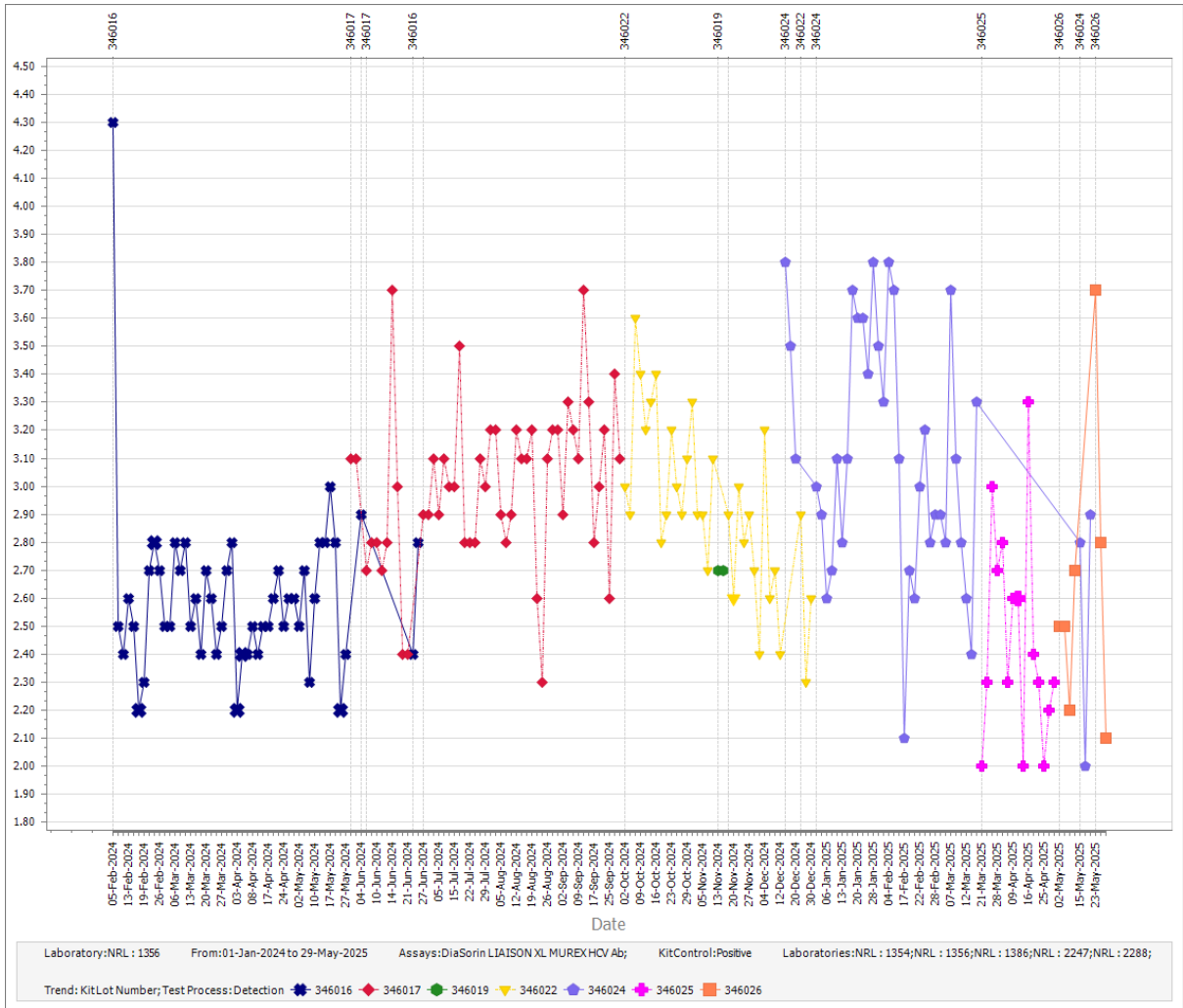


Figure 19- Participant 1356 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for DiaSorin Positive Kit Control.

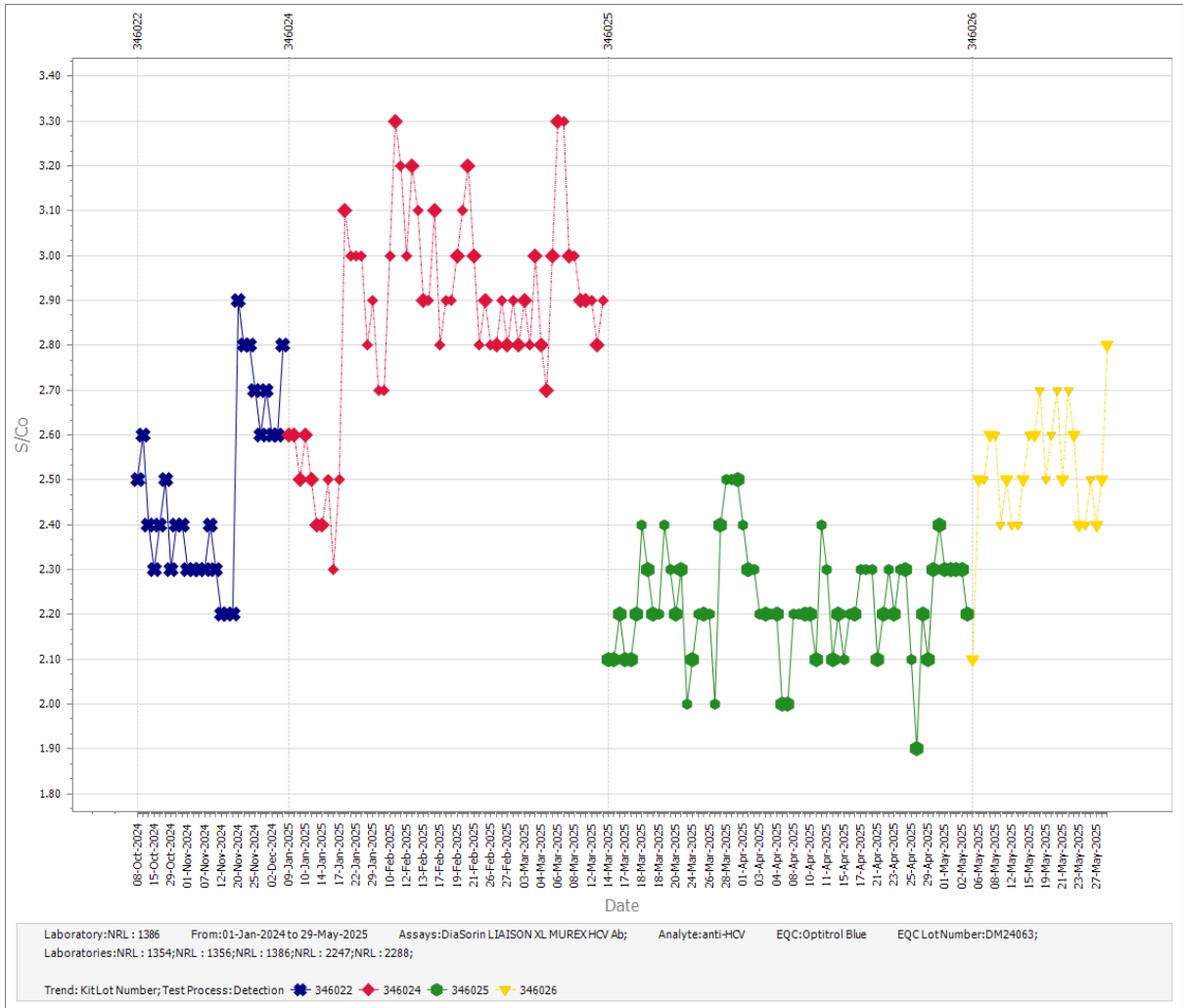


Figure 20- Participant 1386 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.

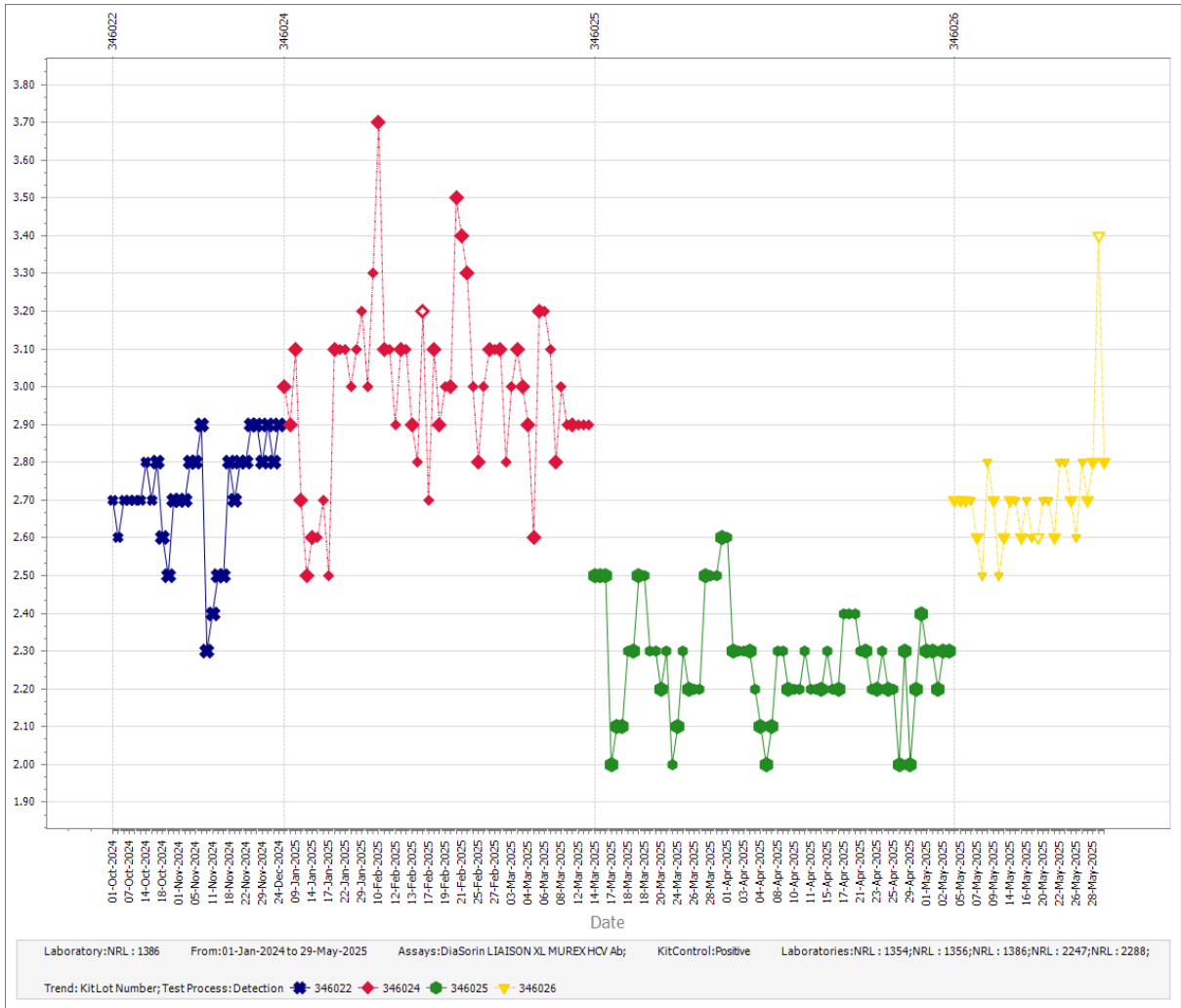


Figure 21- Participant 1386 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for DiaSorin Positive Kit Control.

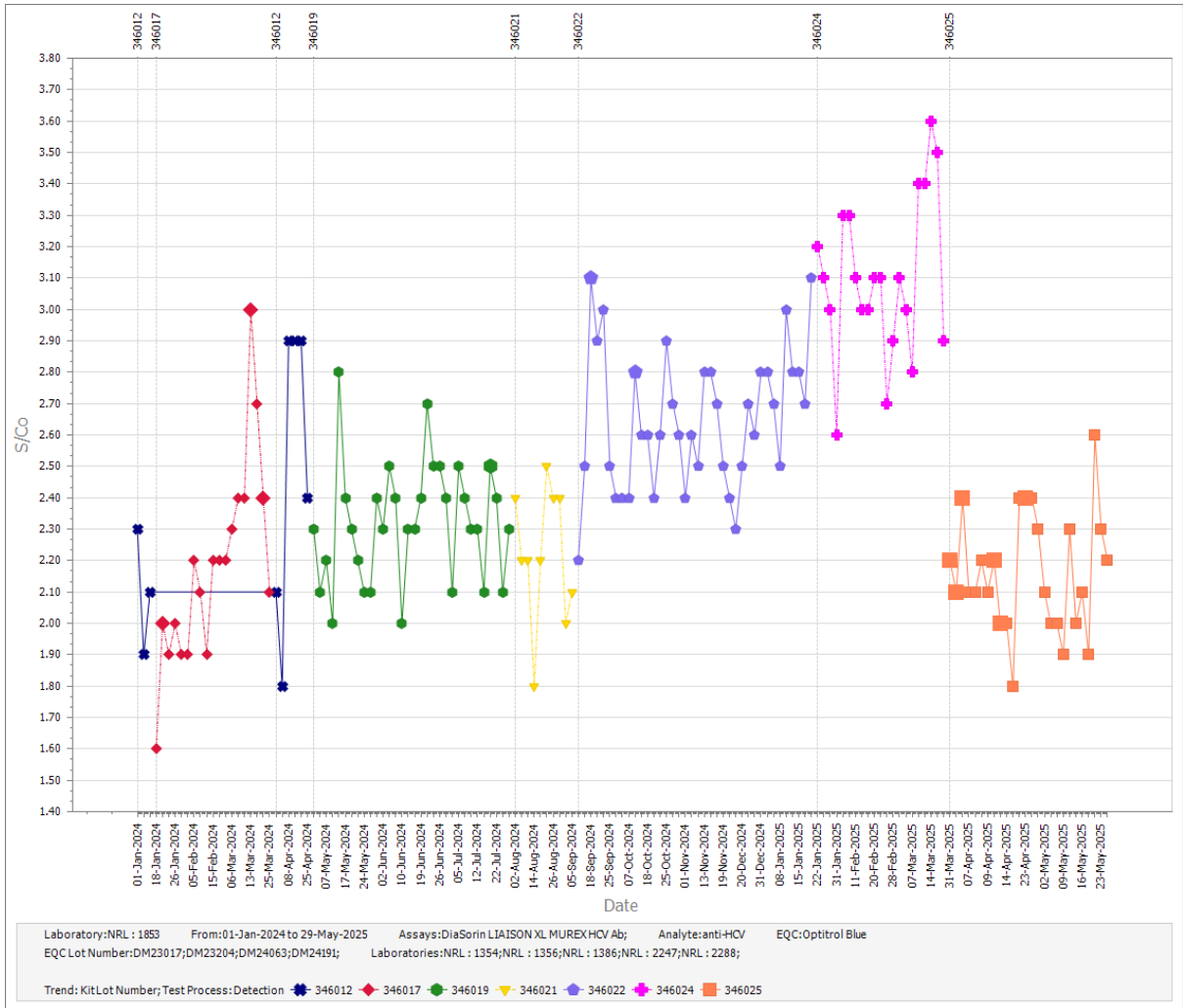


Figure 22- Participant 1853 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue DM24249.

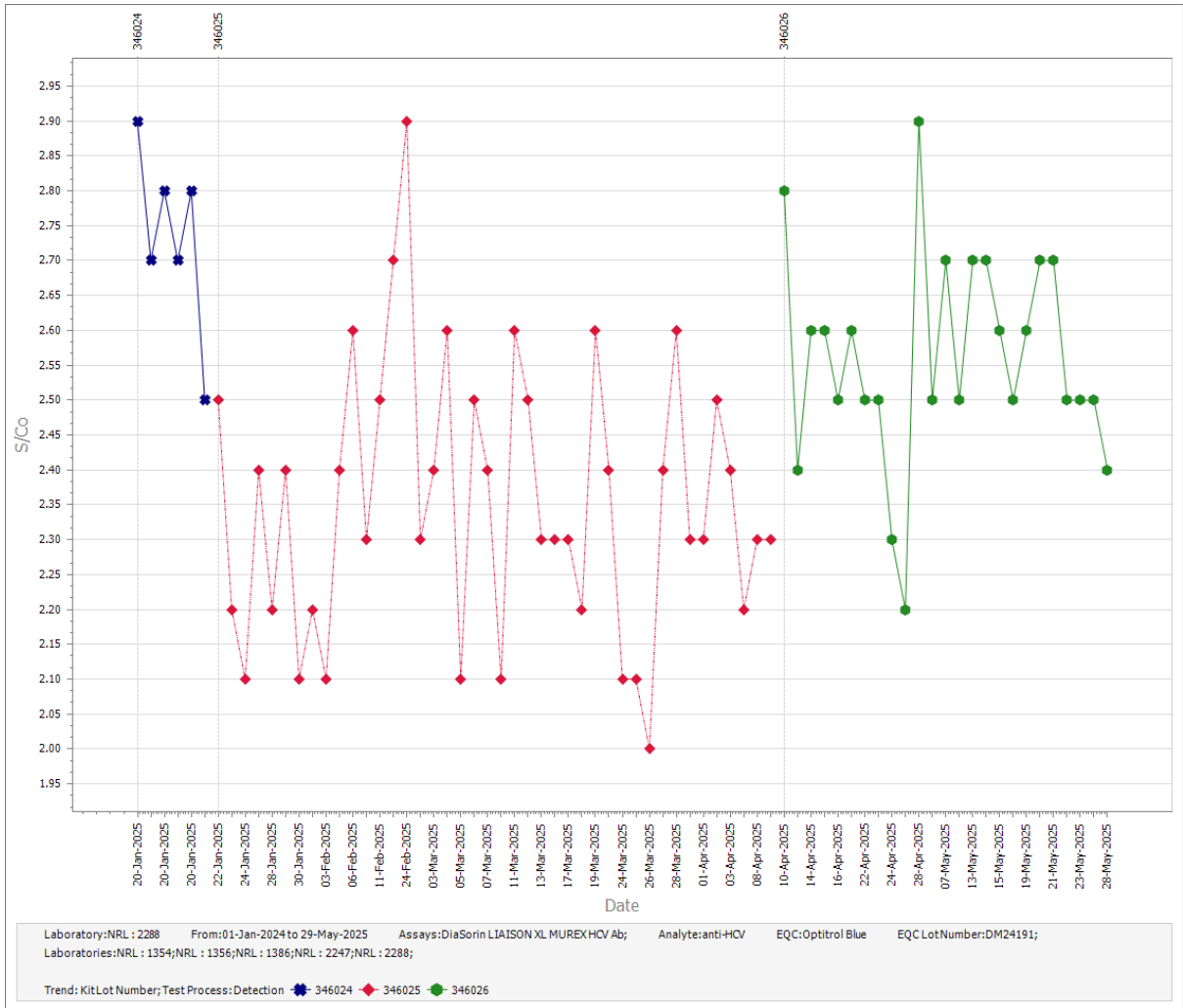


Figure 23- Participant 2288 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for Optitrol Blue.

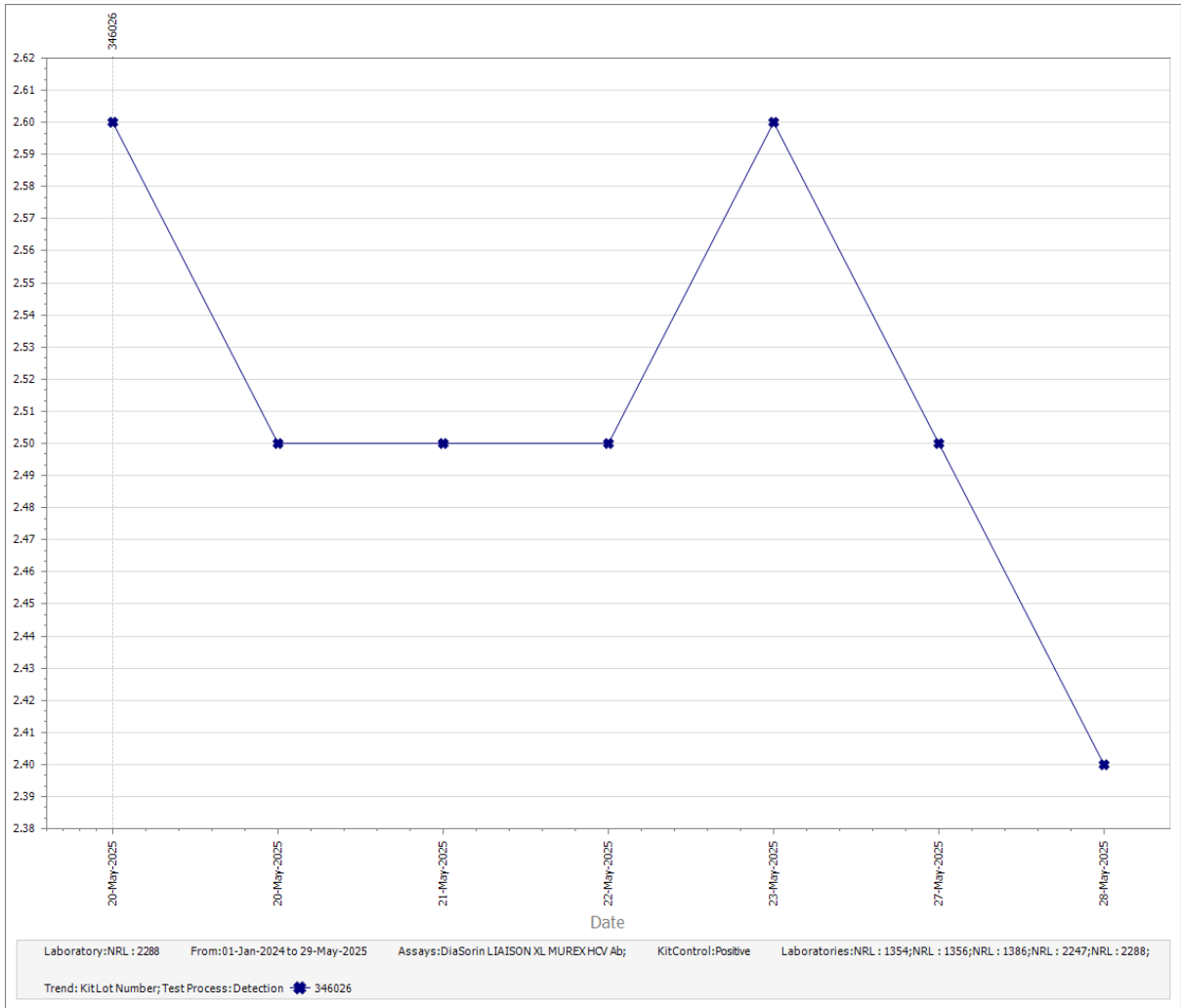


Figure 24- Participant 2288 data reported on the DiaSorin LIAISON XL MUREX HCV Ab assay for DiaSorin Positive Kit Control.

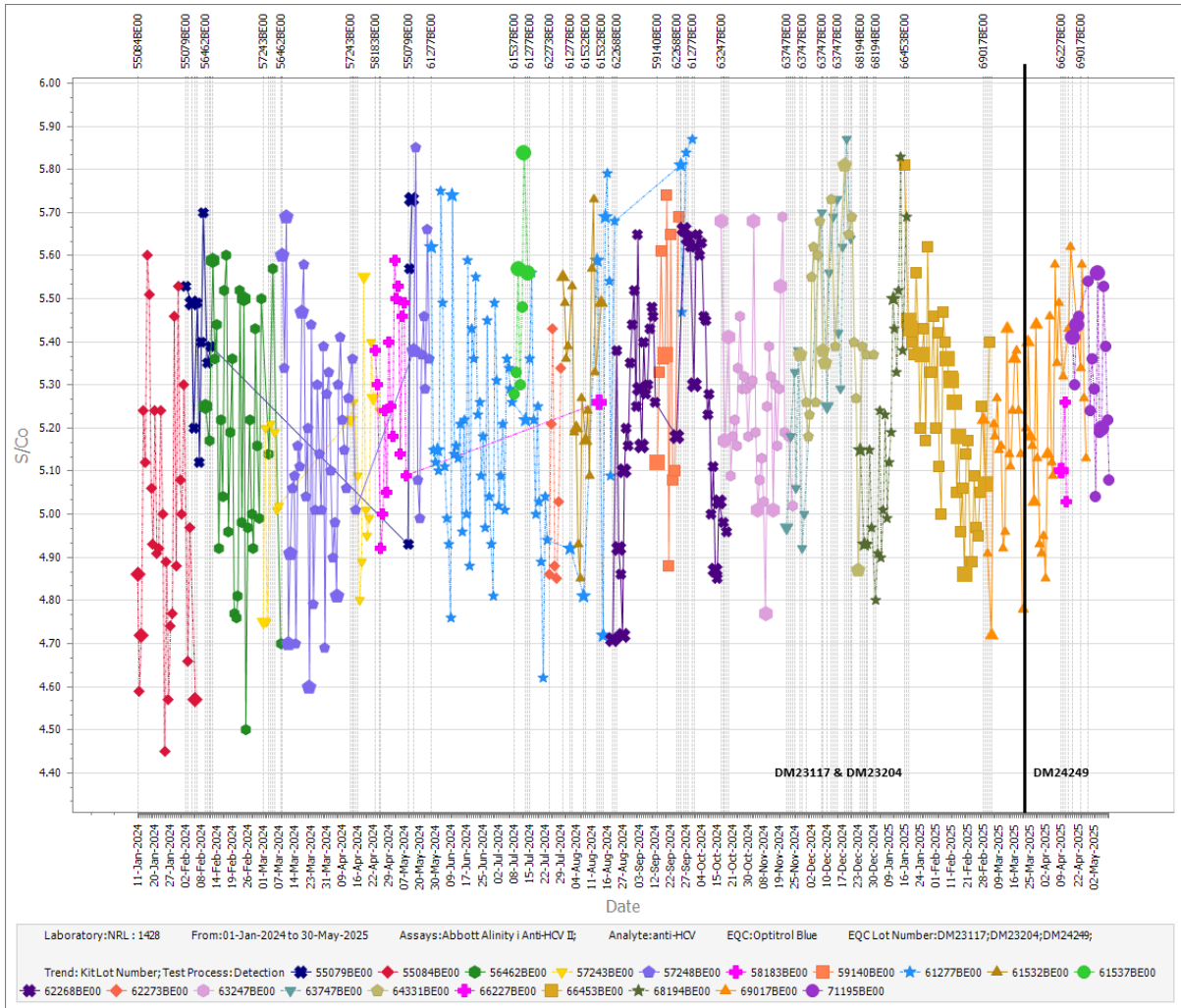


Figure 25- Participant 1428 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

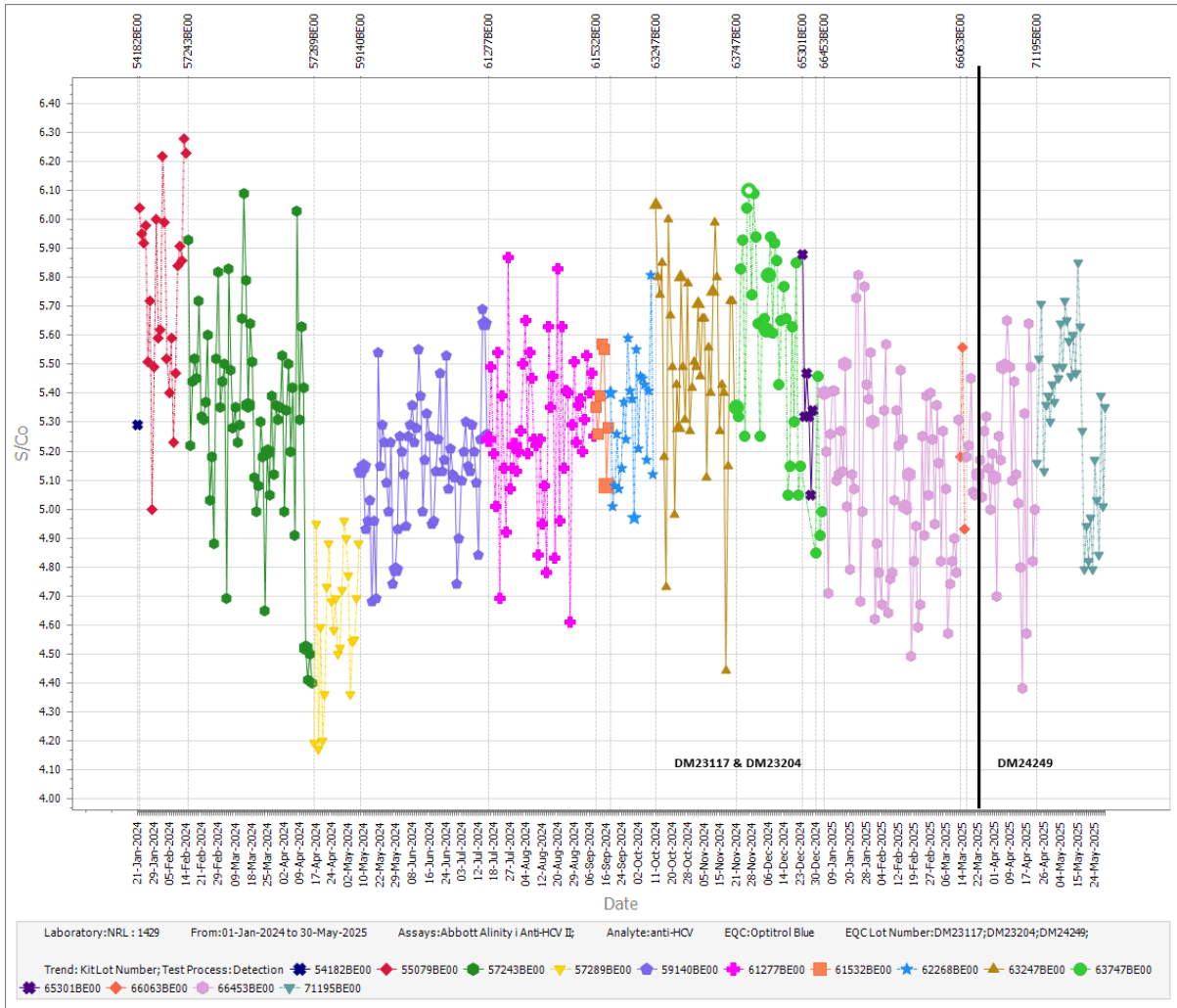


Figure 26- Participant 1429 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

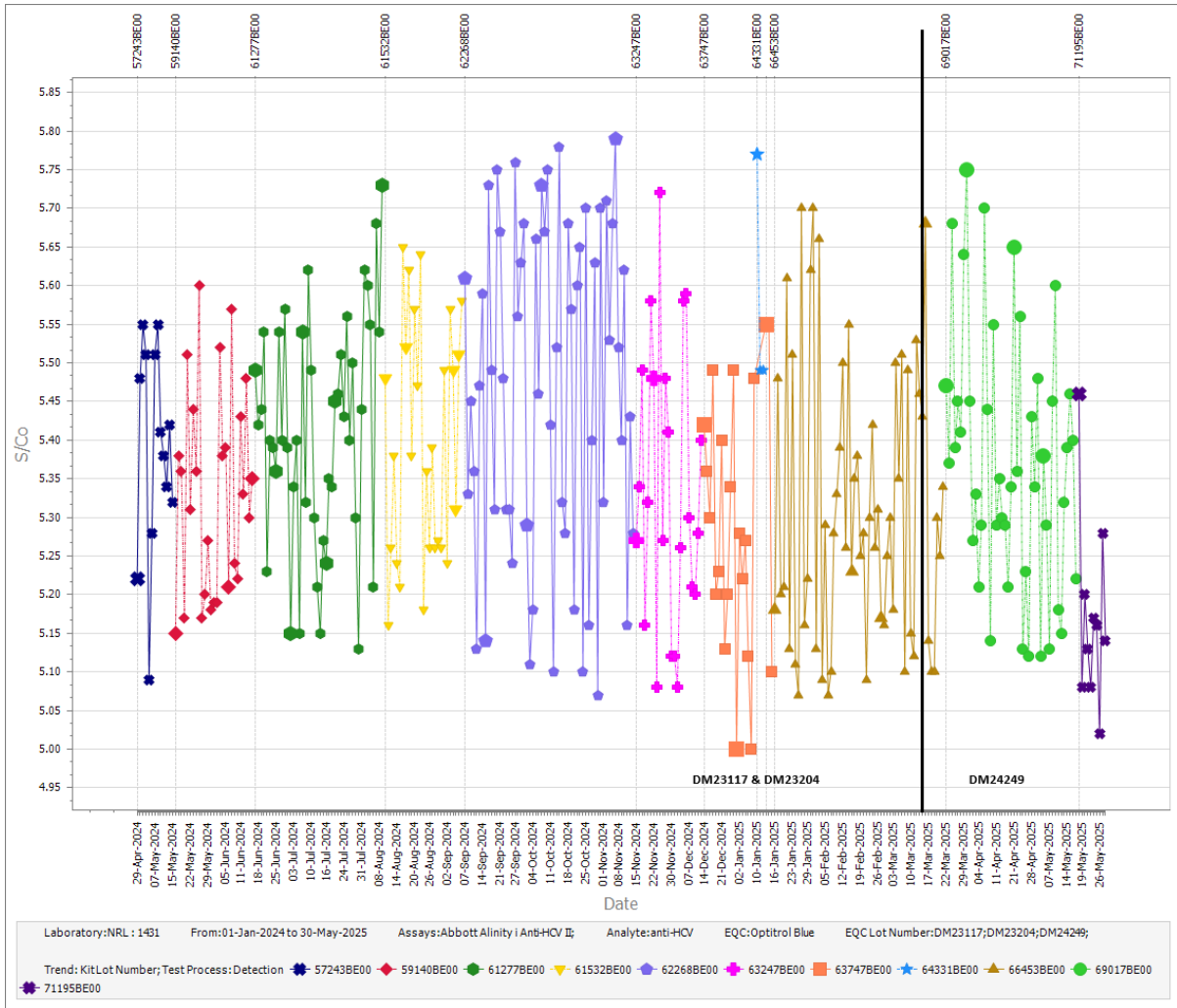


Figure 27- Participant 1431 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

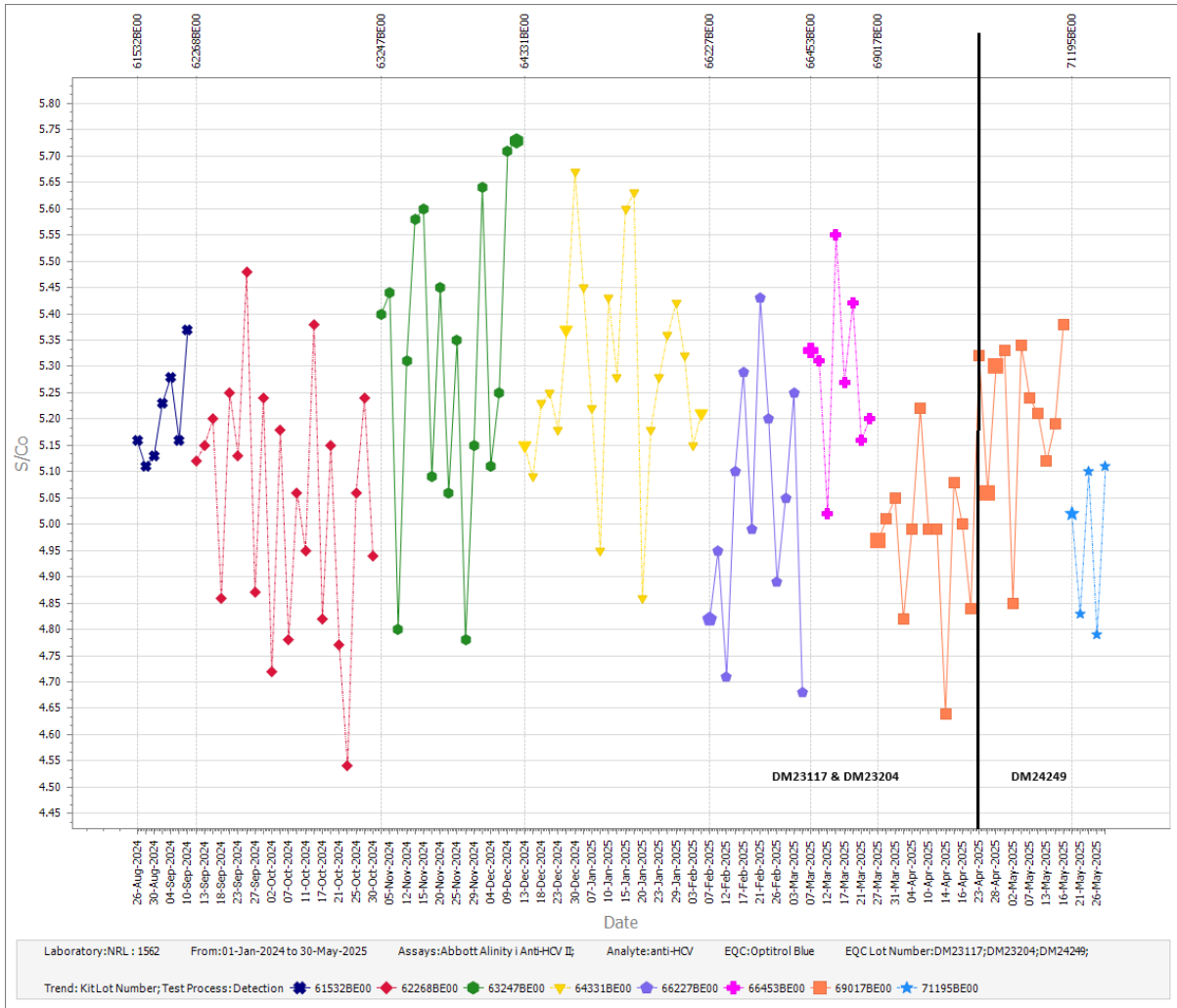


Figure 28- Participant 1562 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

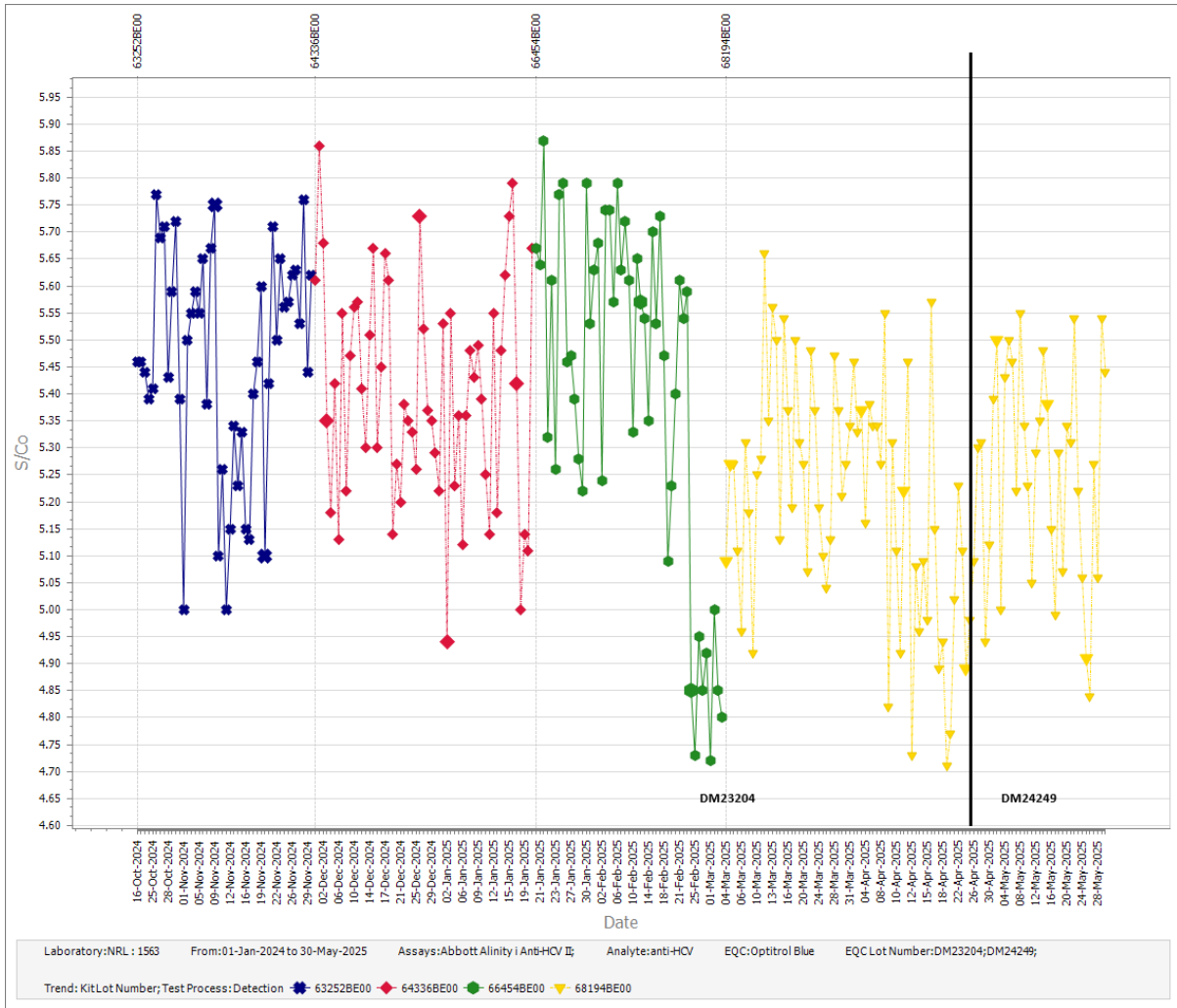


Figure 29- Participant 1563 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

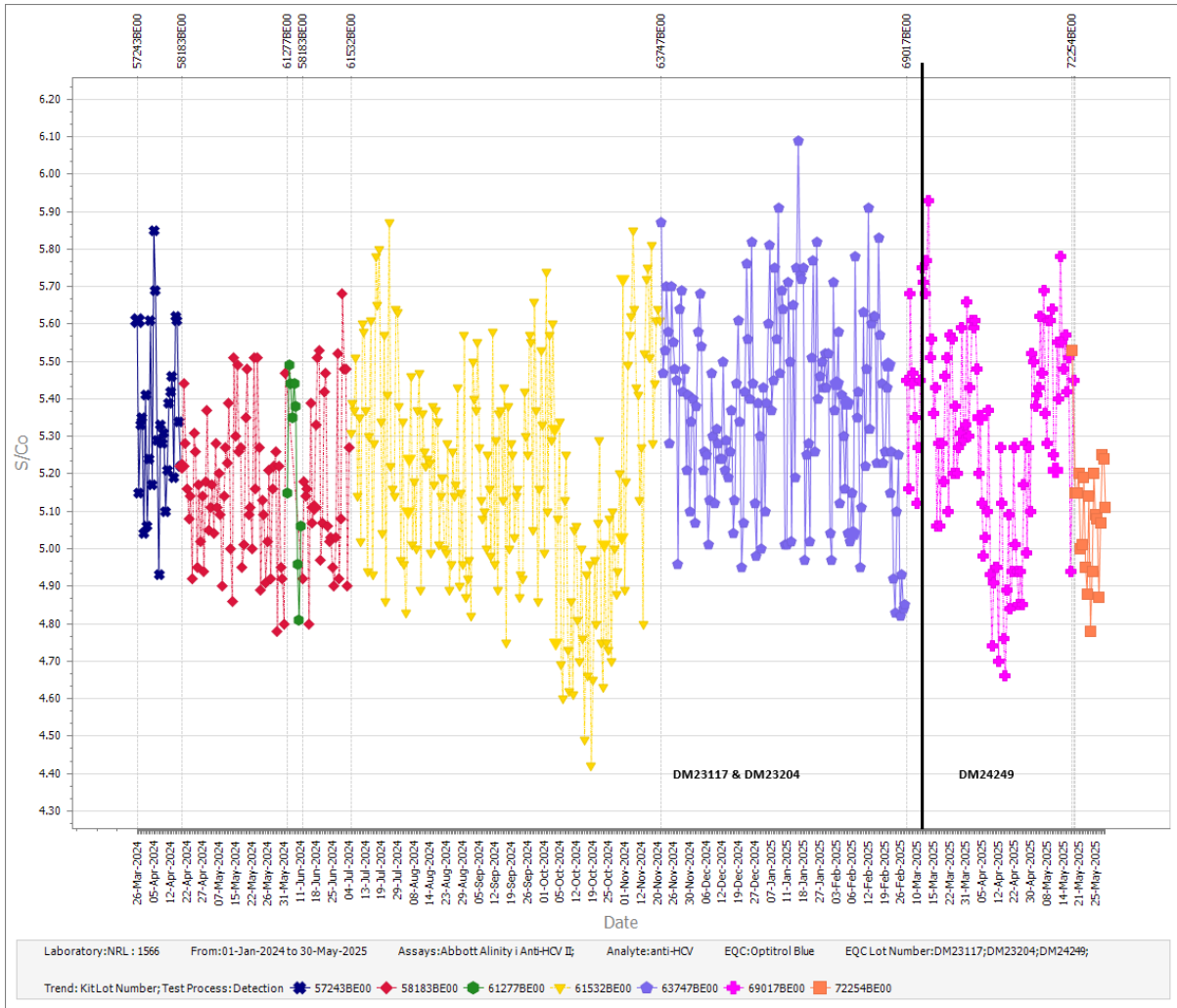


Figure 30- Participant 1556 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

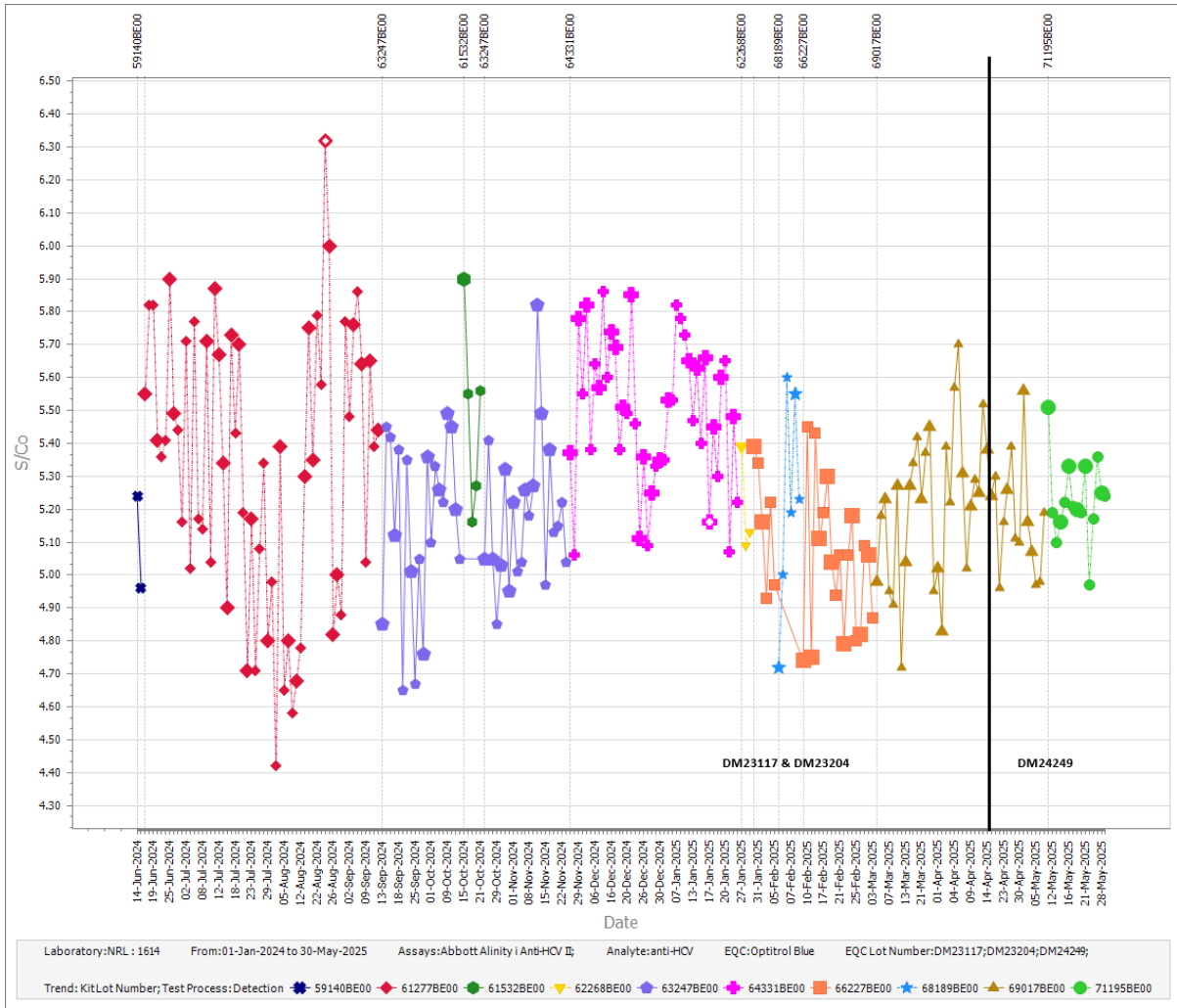


Figure 31- Participant 1614 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

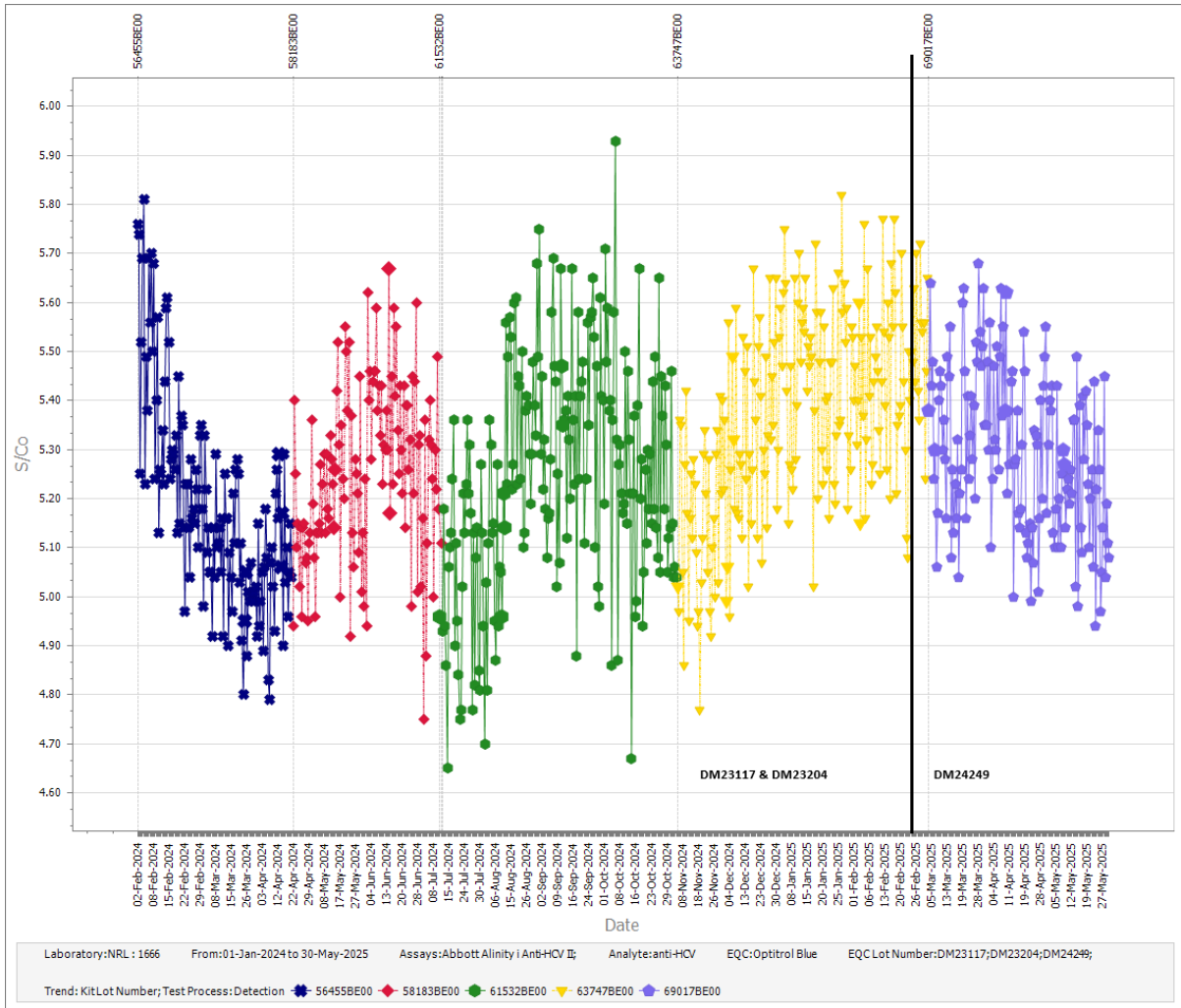


Figure 32- Participant 1666 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

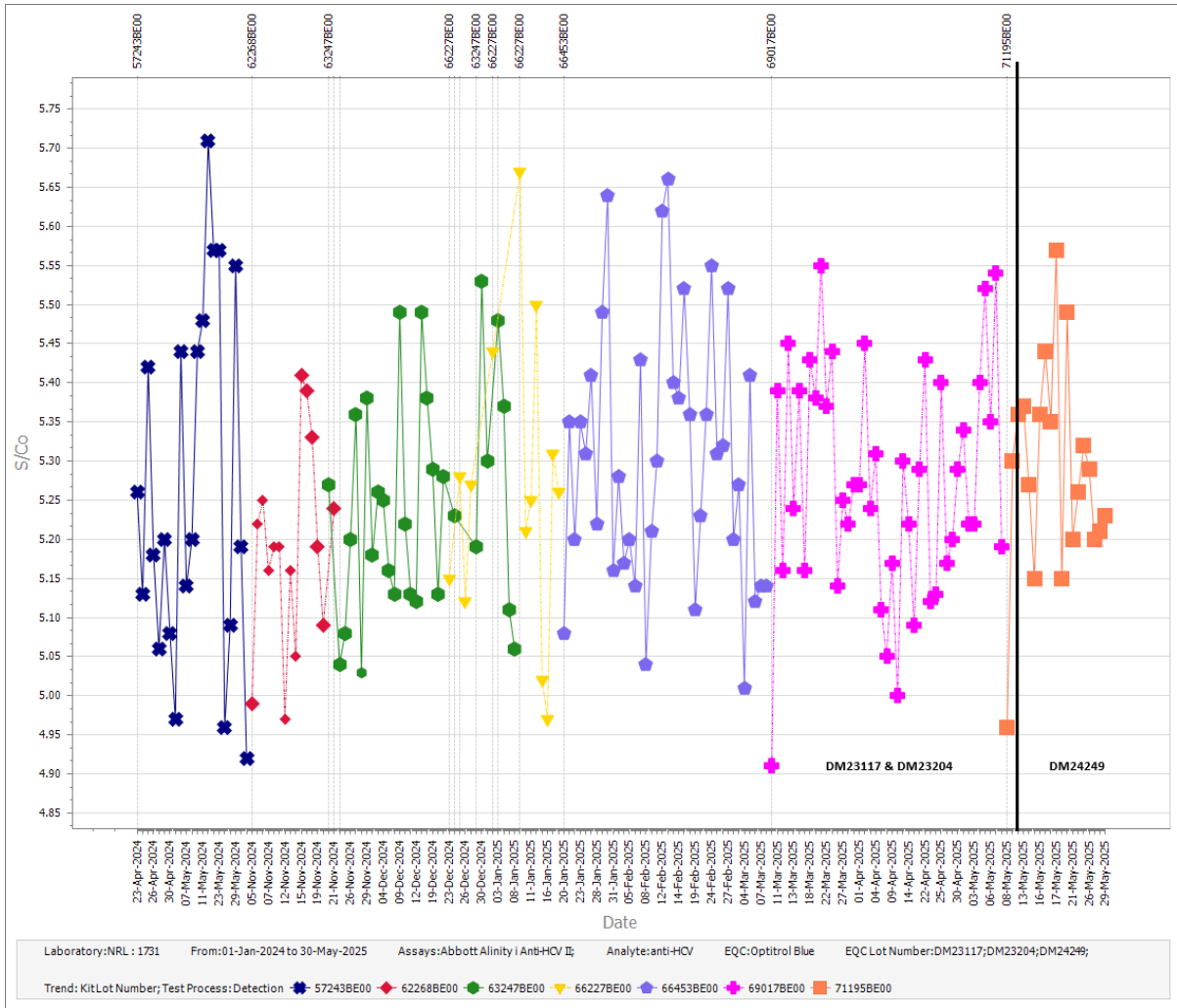


Figure 33- Participant 1731 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

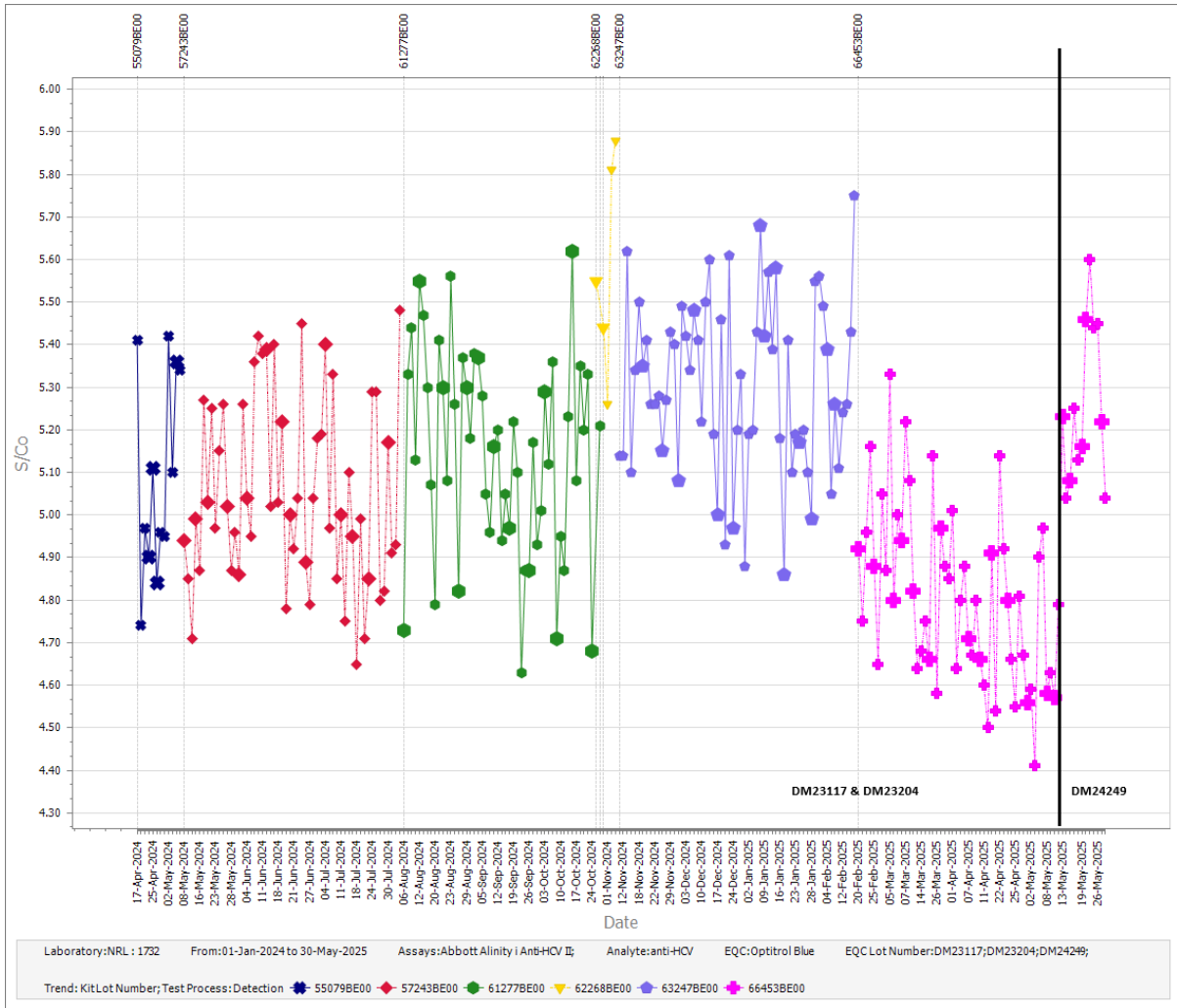


Figure 34- Participant 1732 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

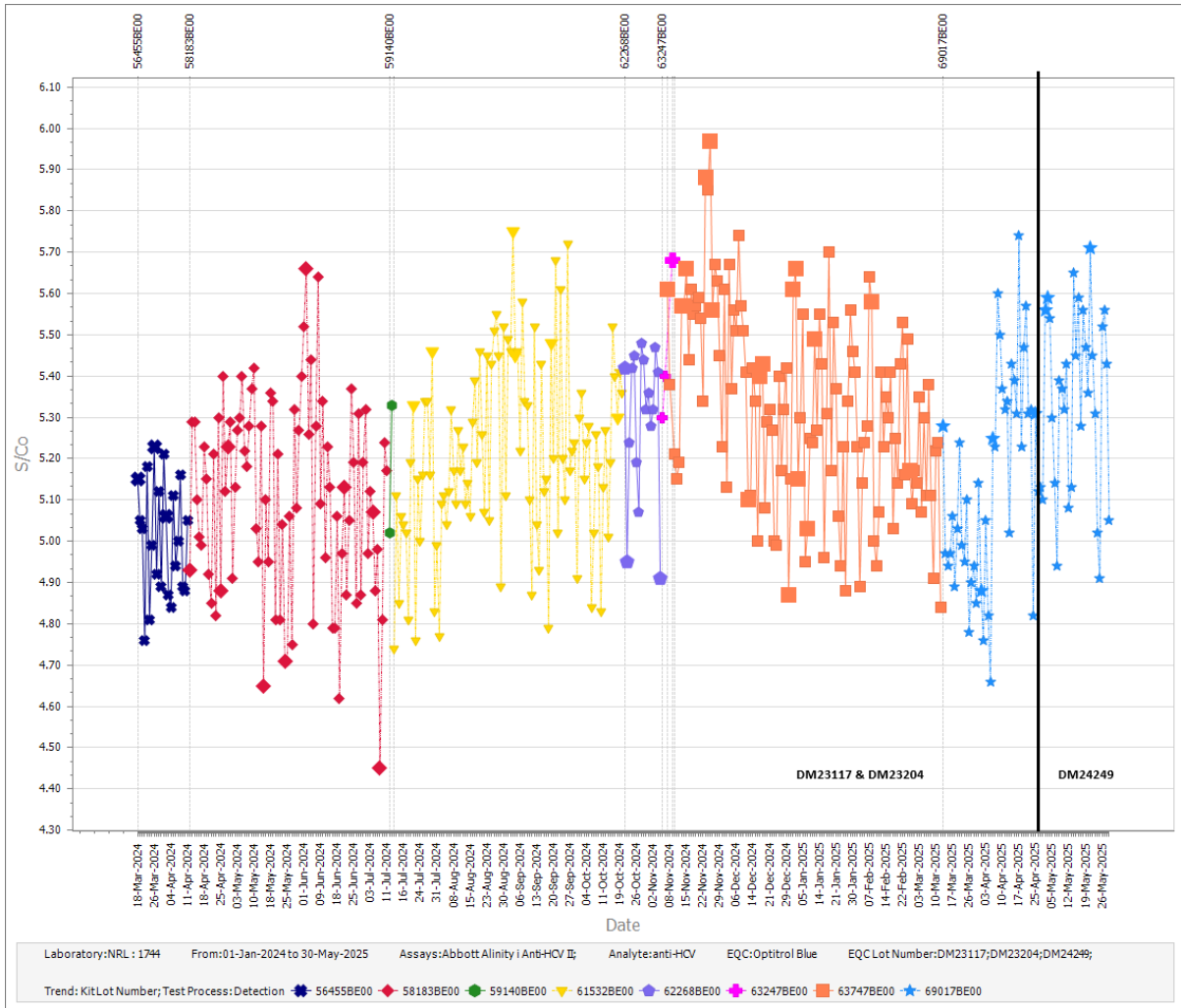


Figure 35- Participant 1744 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

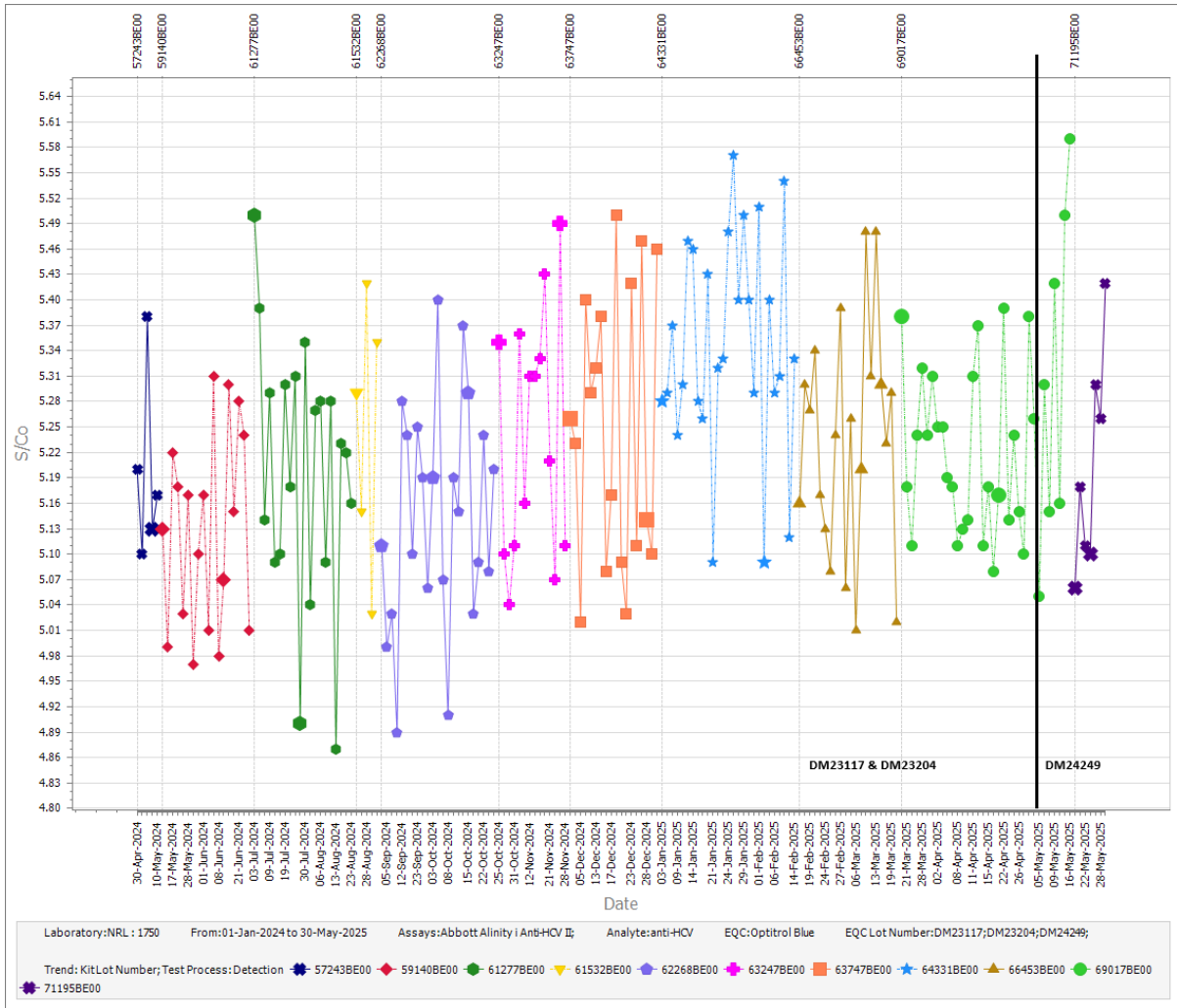


Figure 36- Participant 1750 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

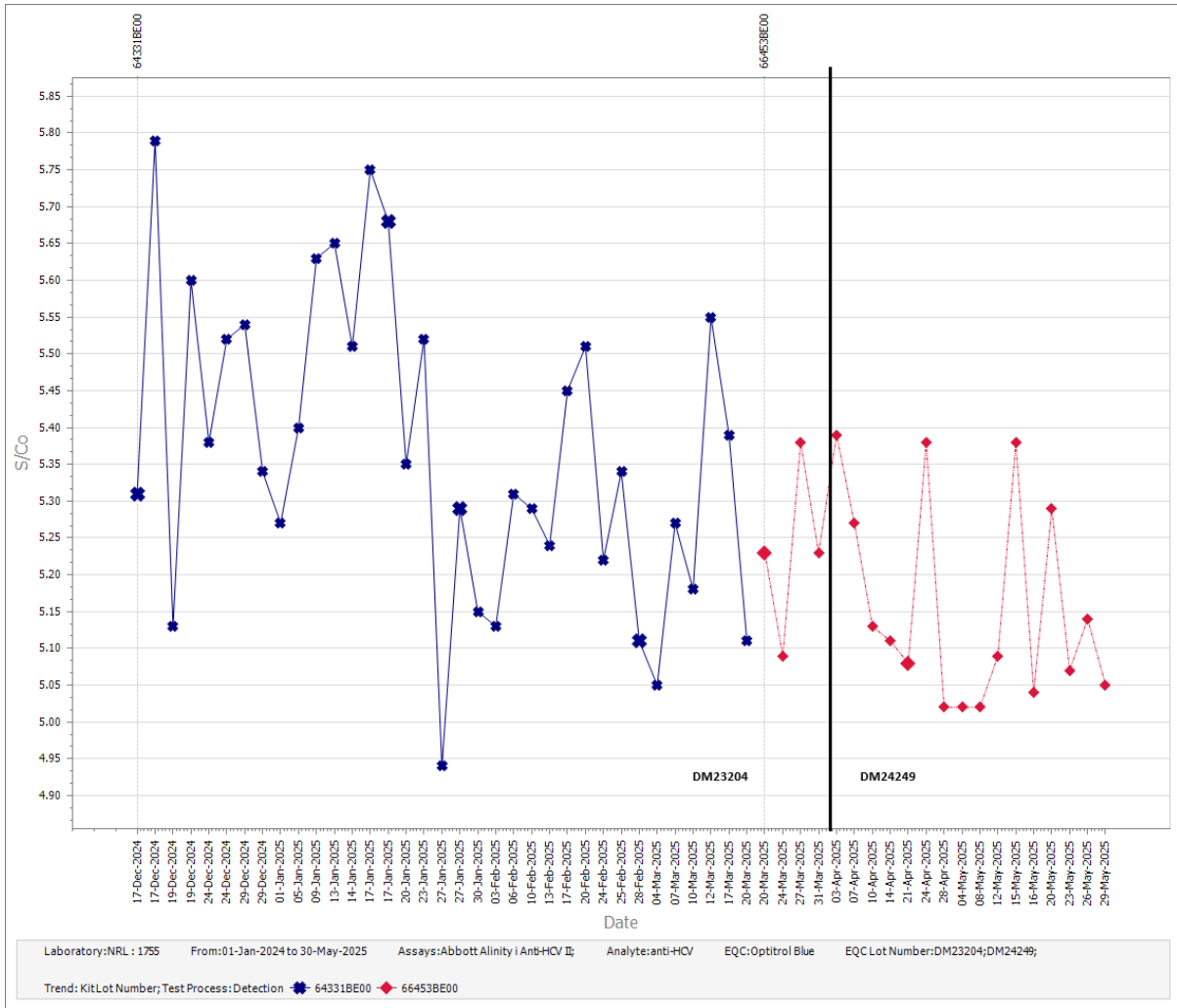


Figure 37- Participant 1755 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

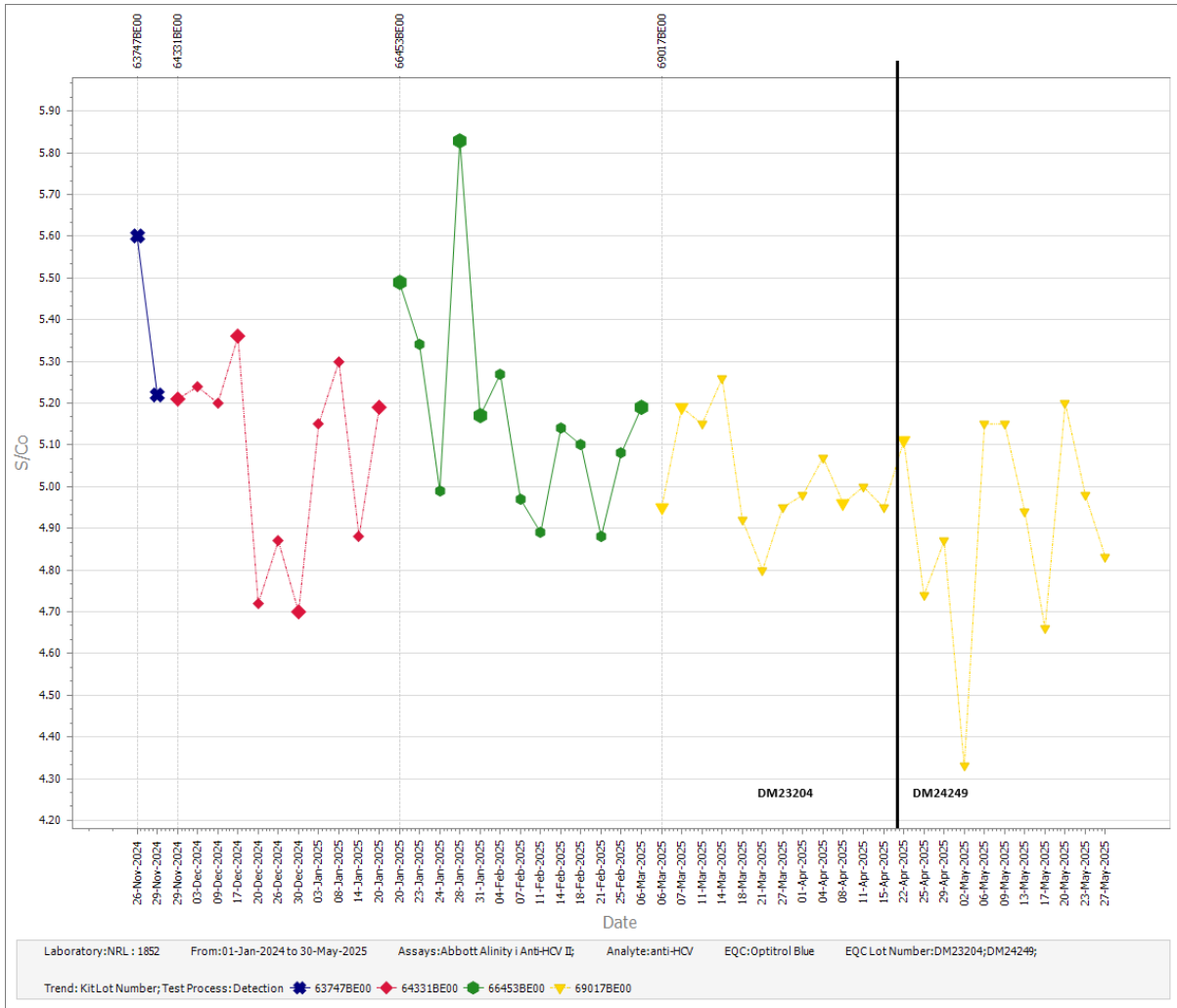


Figure 38- Participant 1852 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

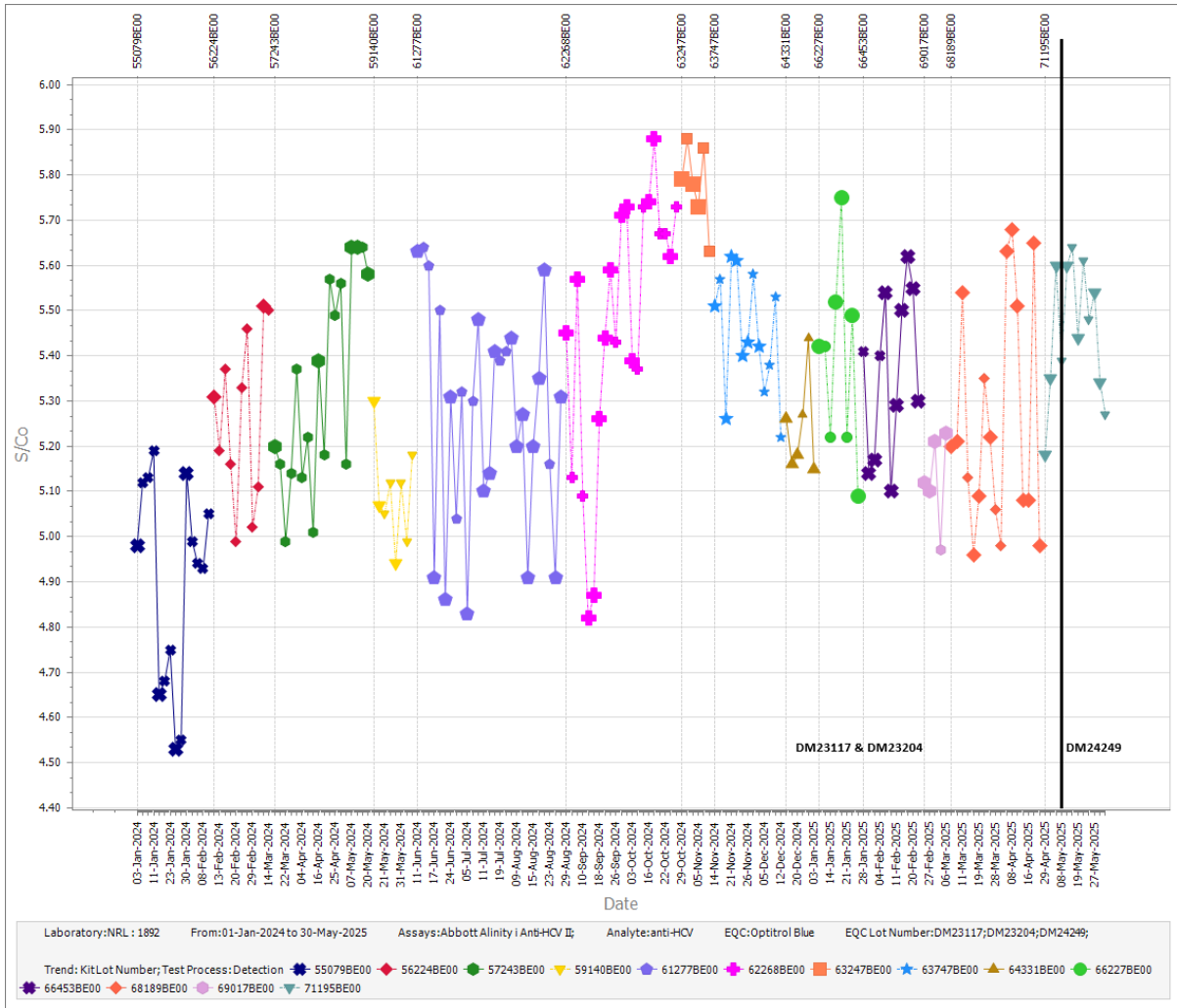


Figure 39- Participant 1892 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

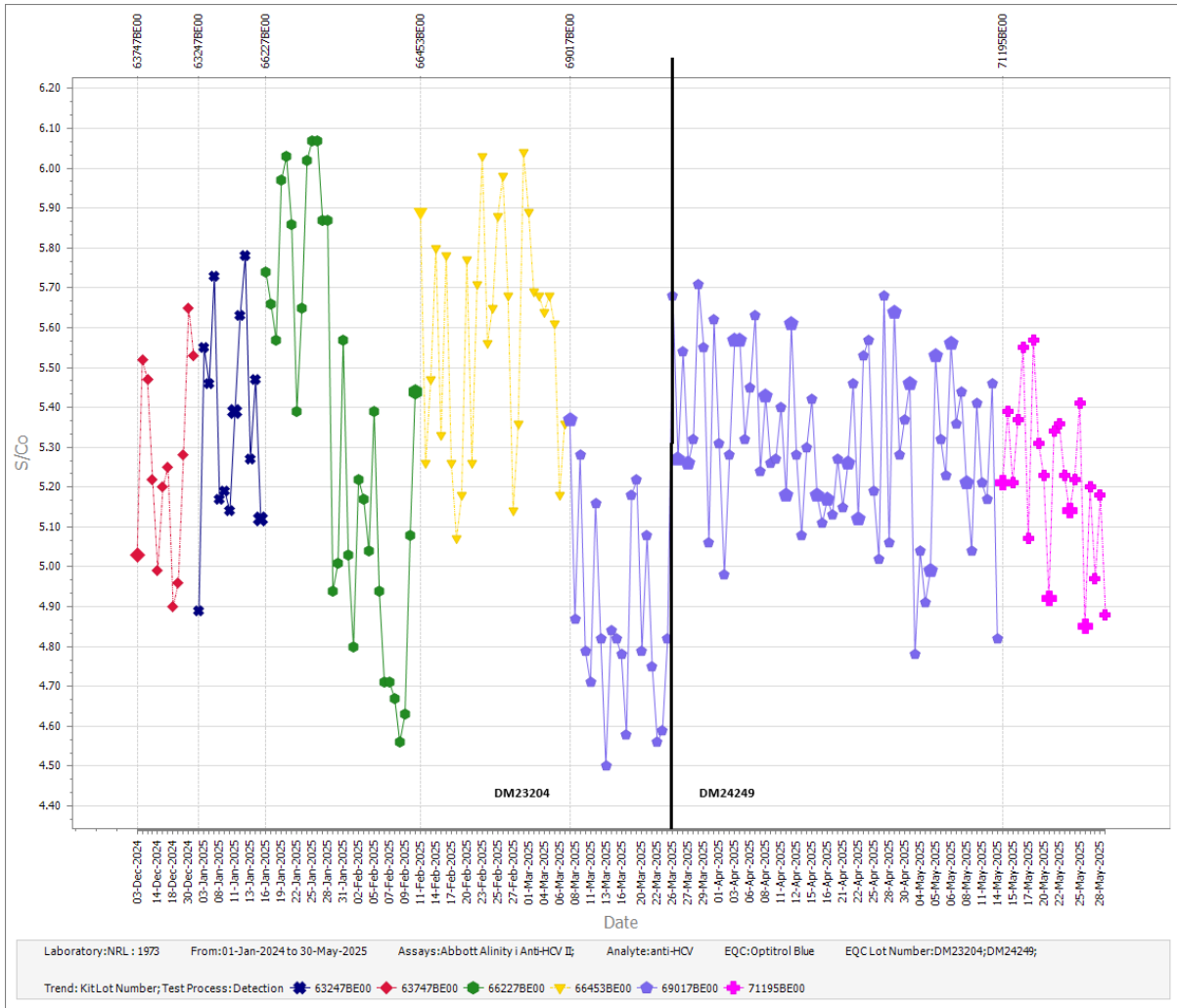


Figure 40- Participant 1973 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

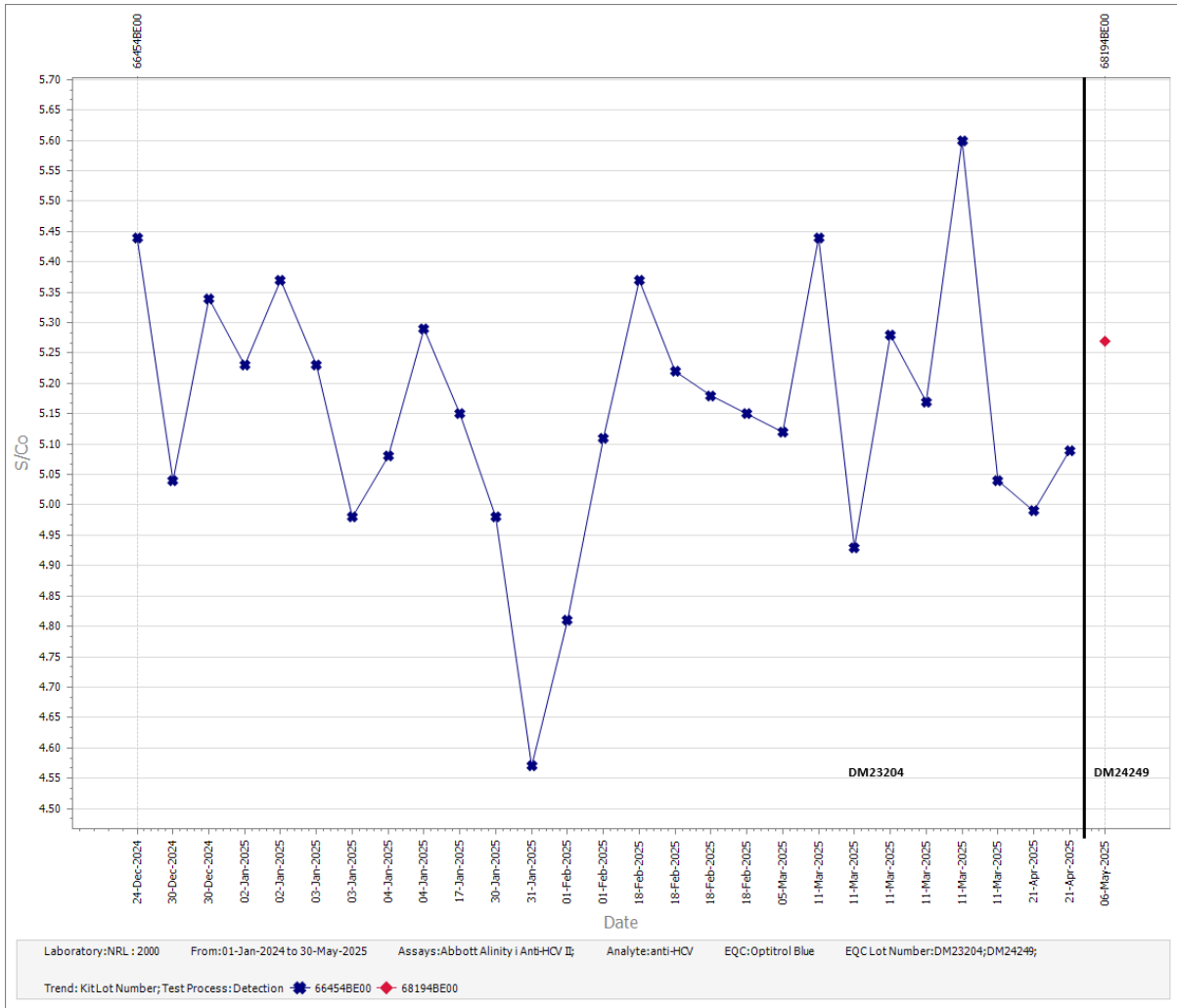


Figure 41- Participant 2000 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

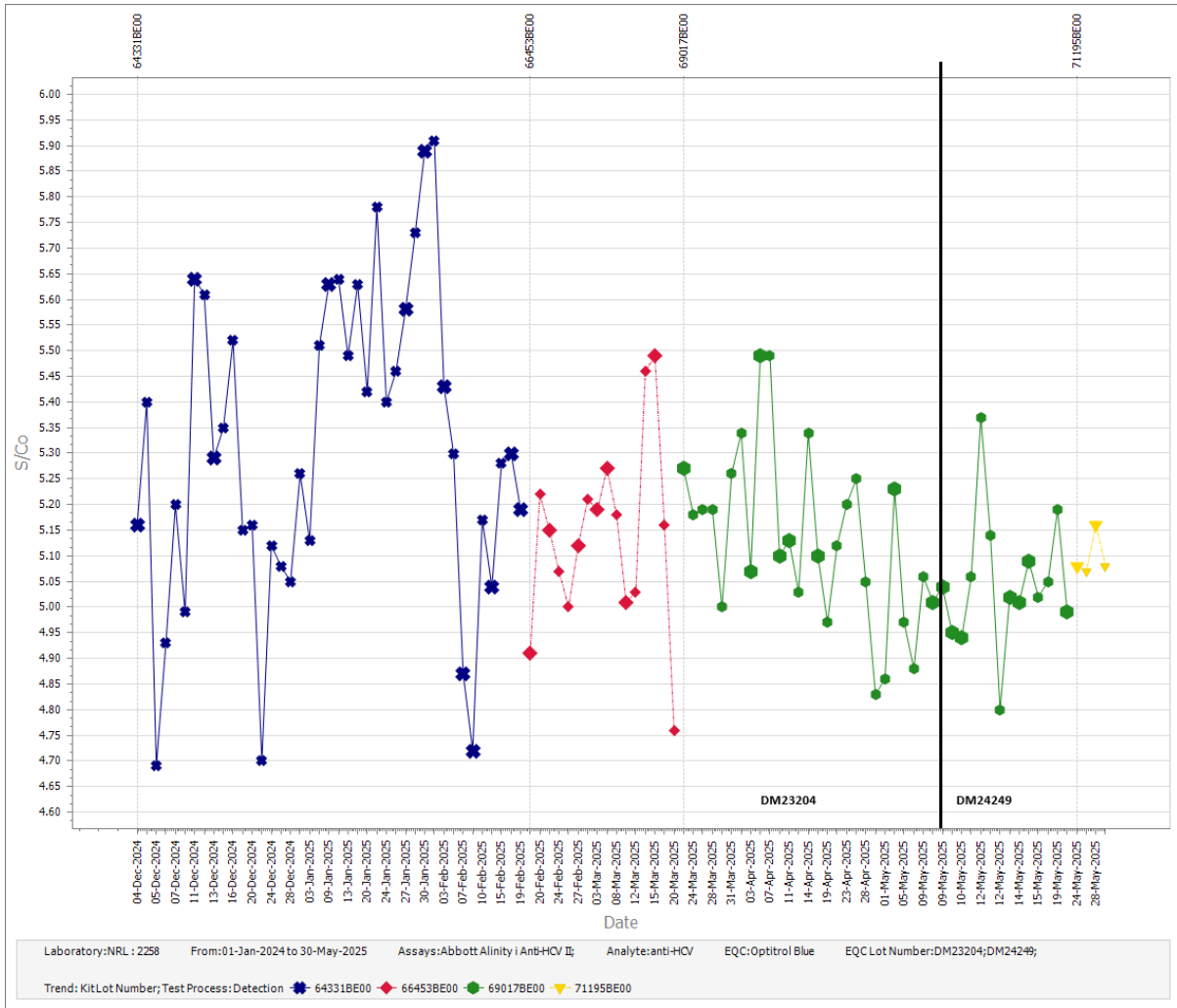


Figure 42- Participant 2258 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

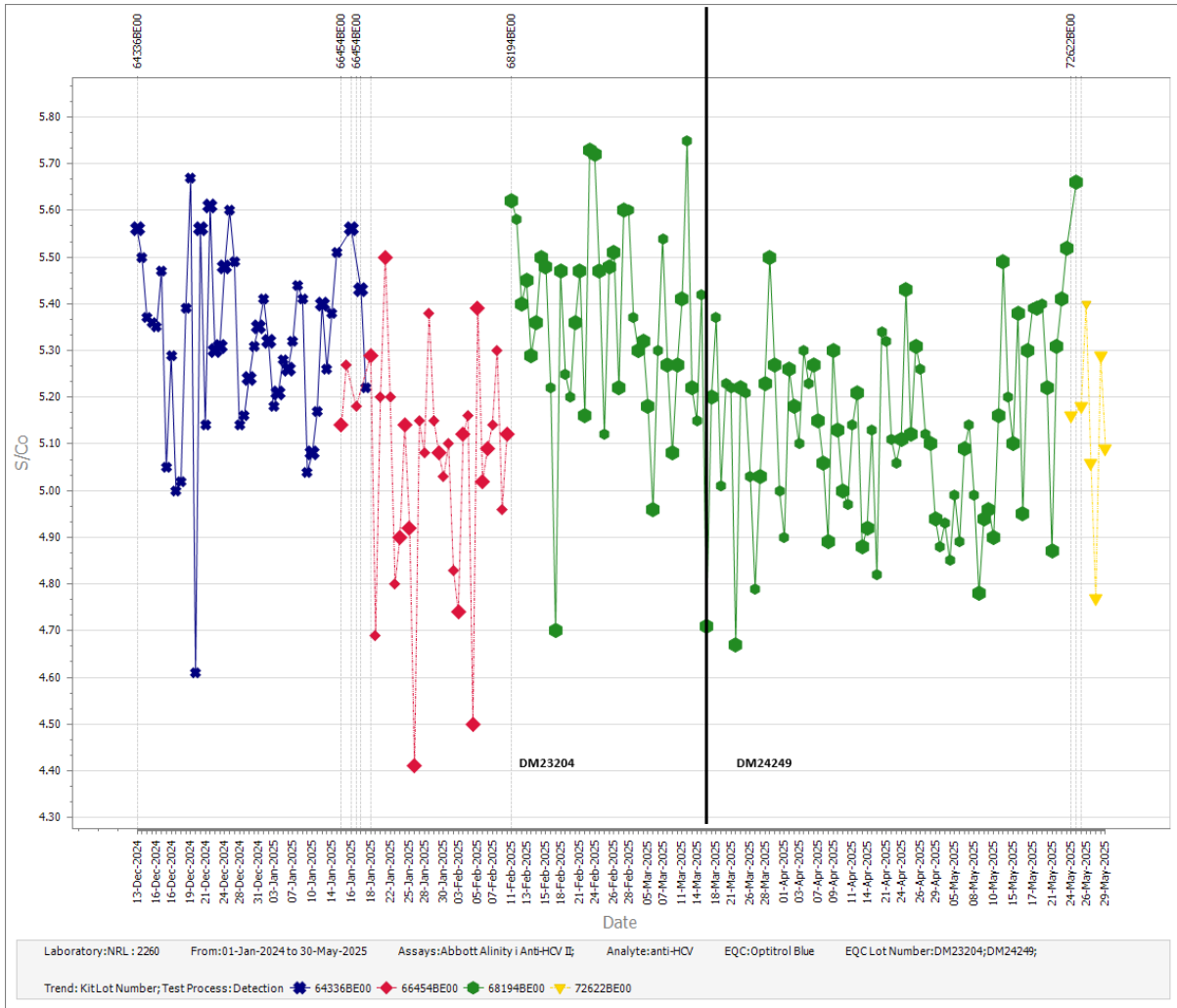


Figure 43- Participant 2260 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

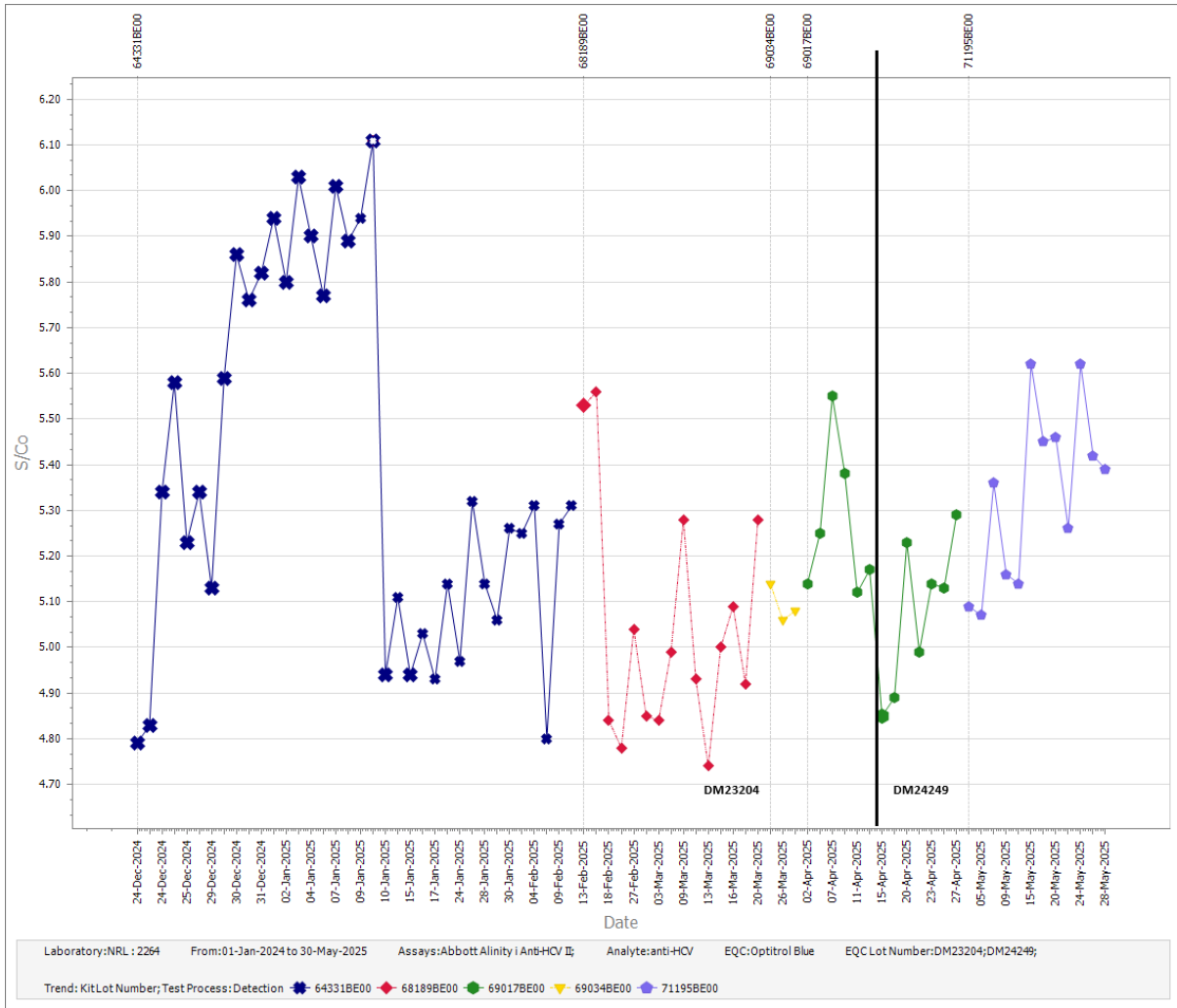


Figure 44- Participant 2264 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

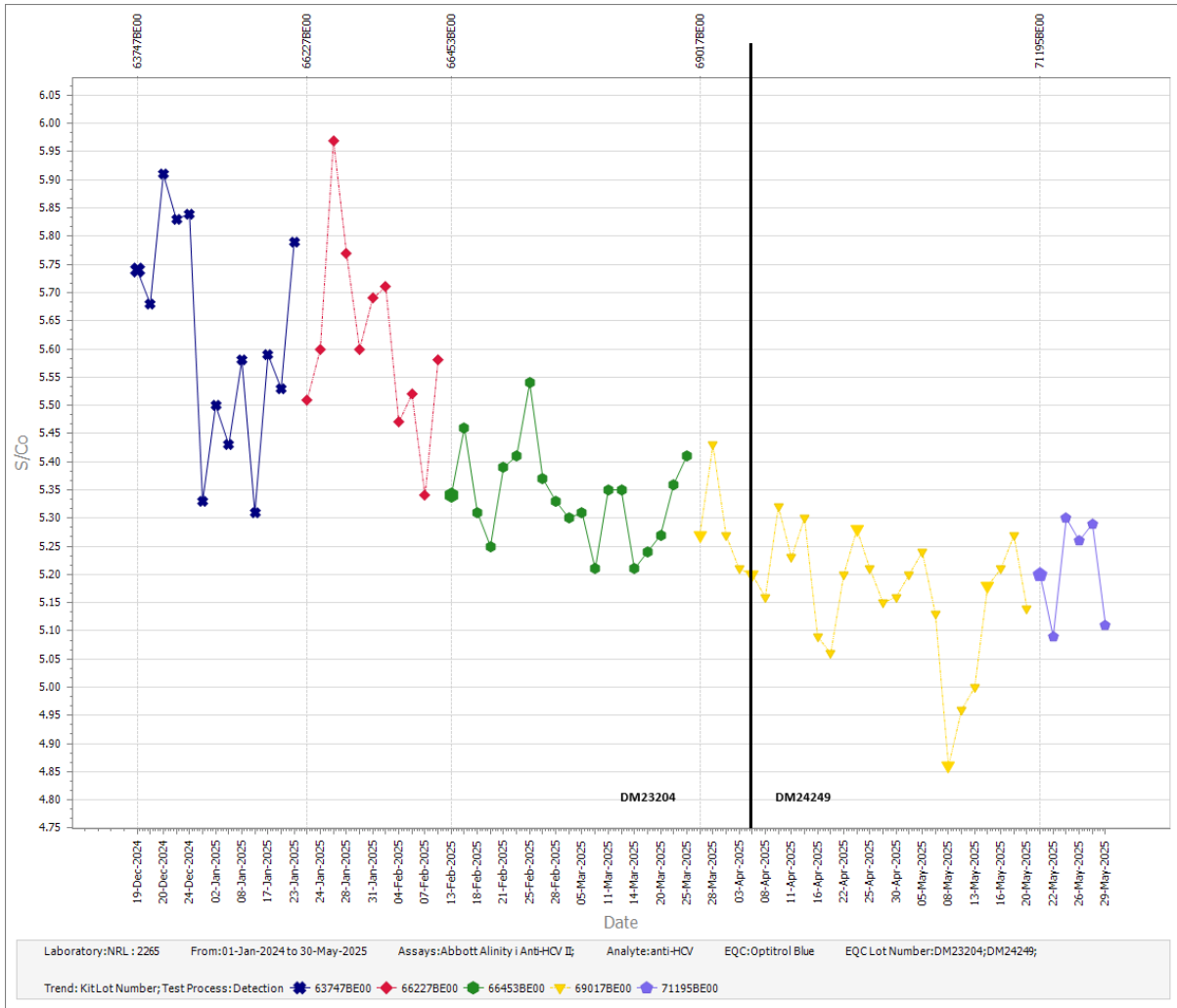


Figure 45- Participant 2265 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

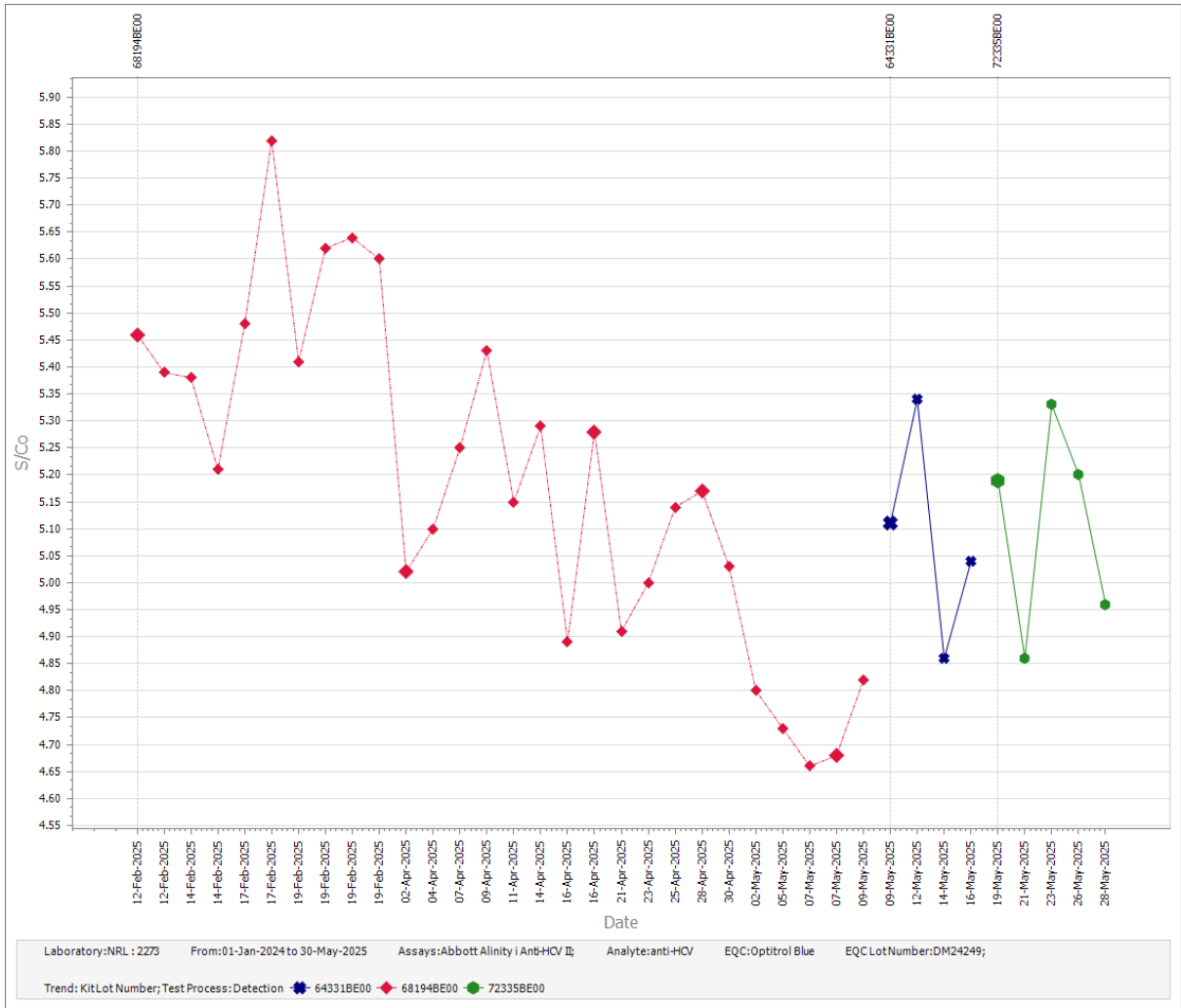


Figure 46- Participant 2273 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

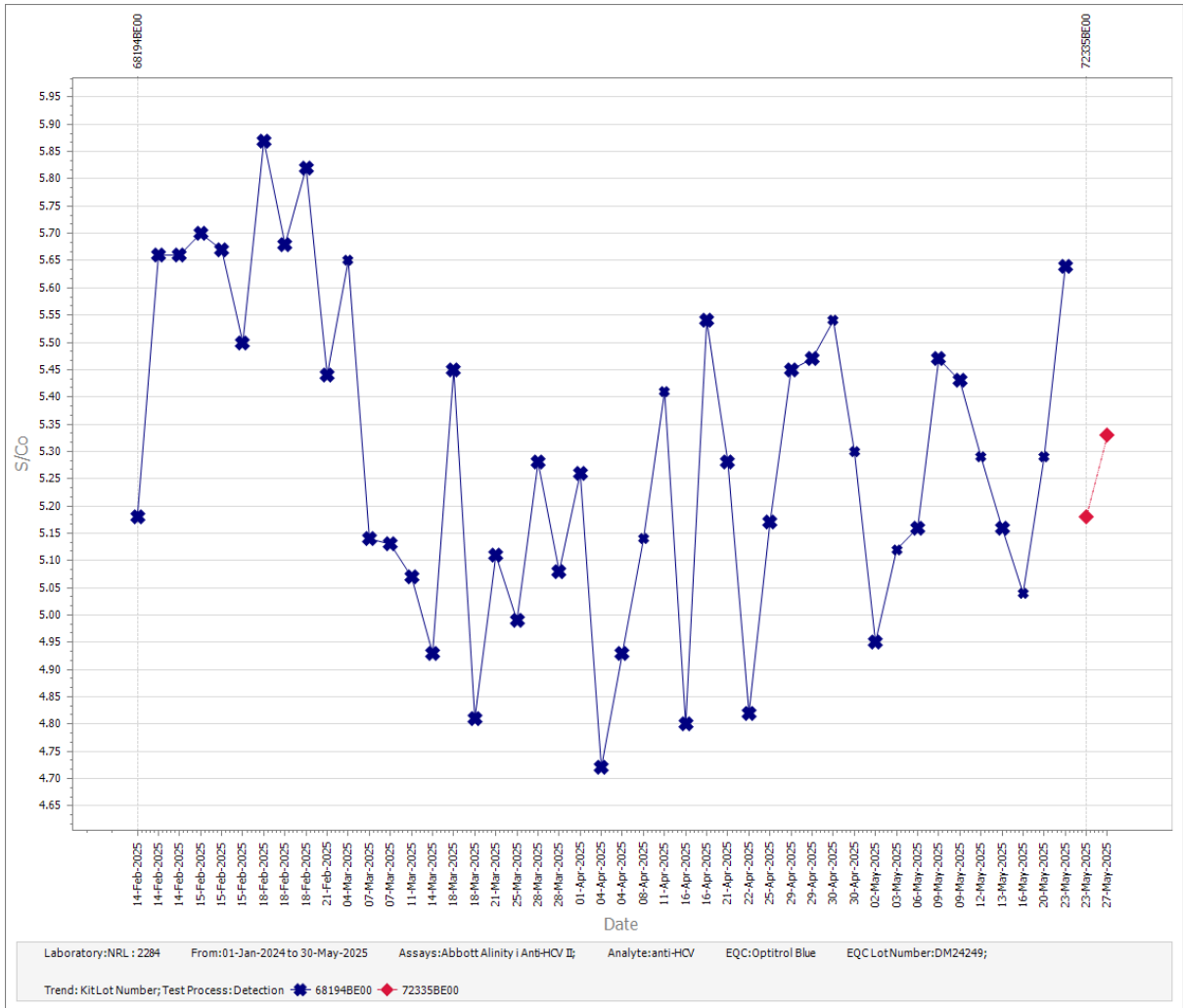


Figure 47- Participant 2284 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

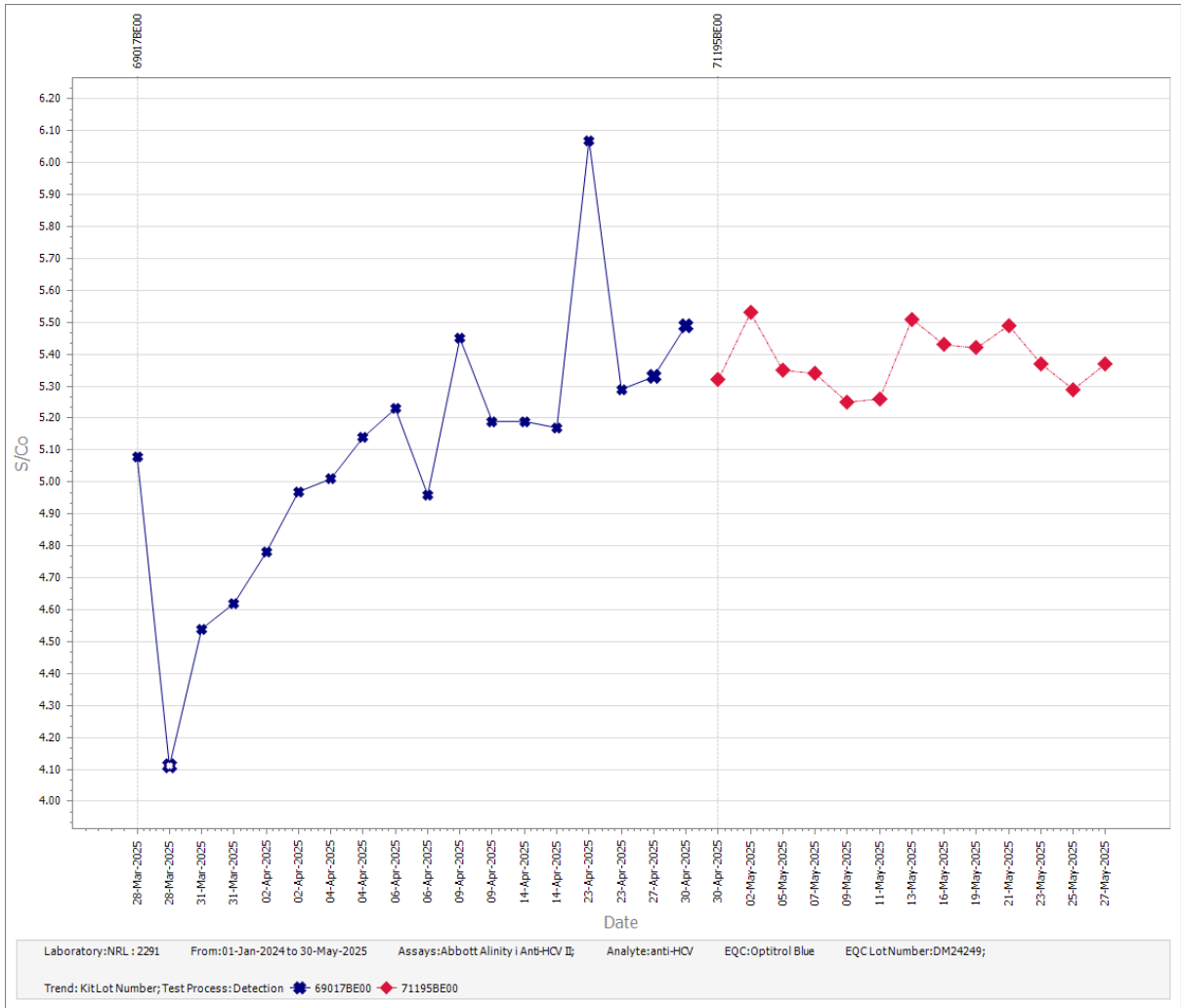


Figure 48- Participant 2291 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue.

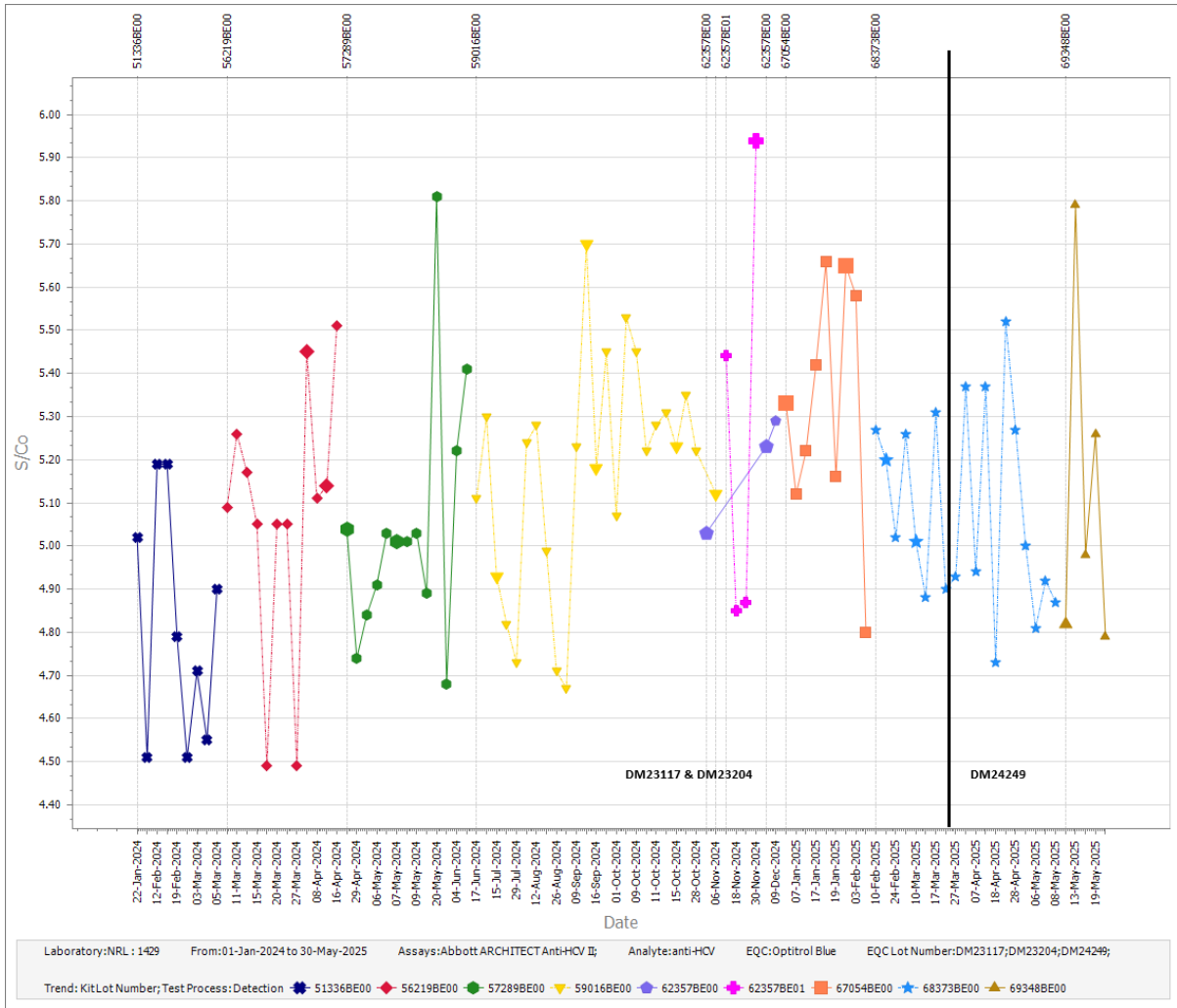


Figure 49- Participant 1429 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

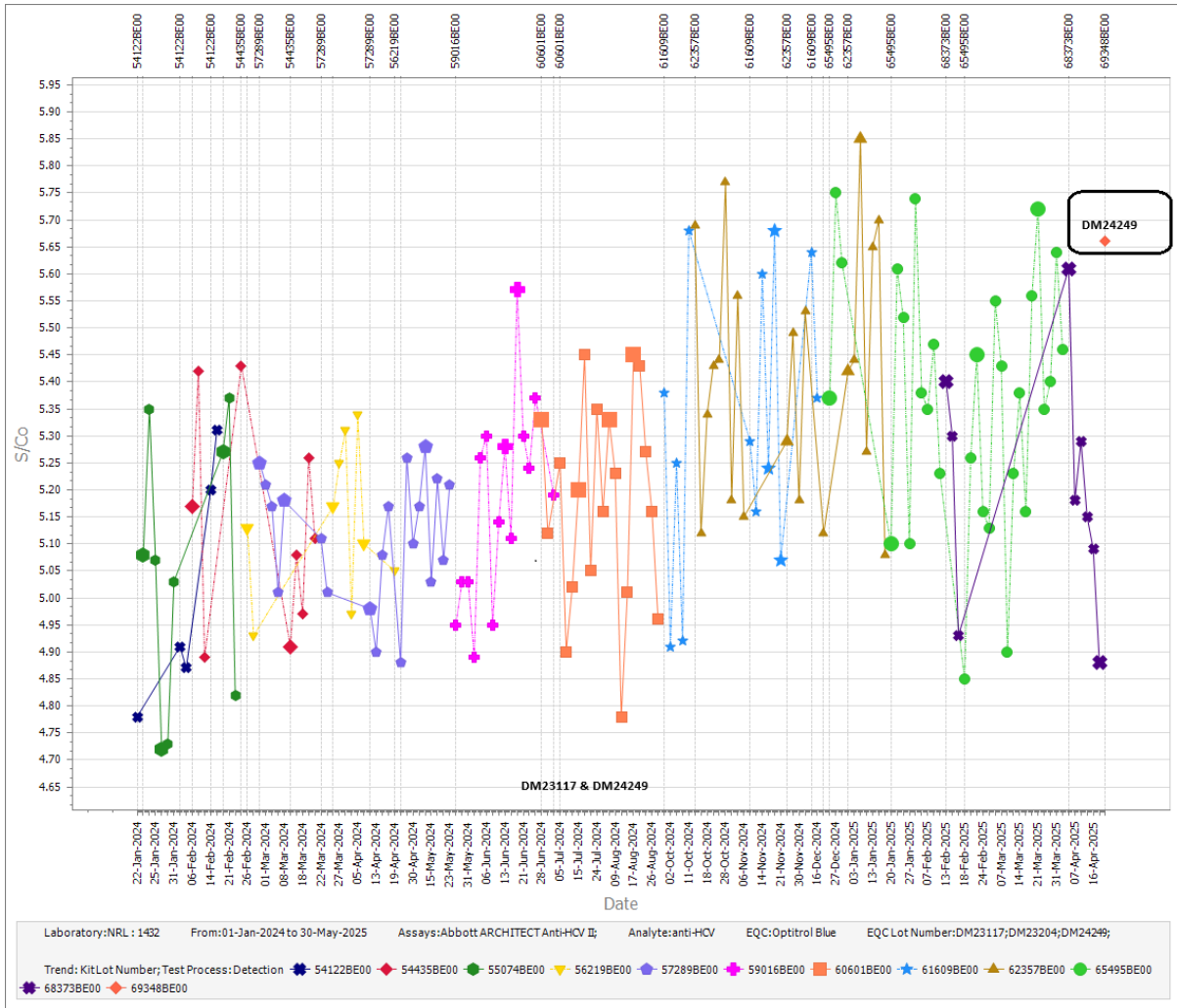


Figure 50- Participant 1432 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

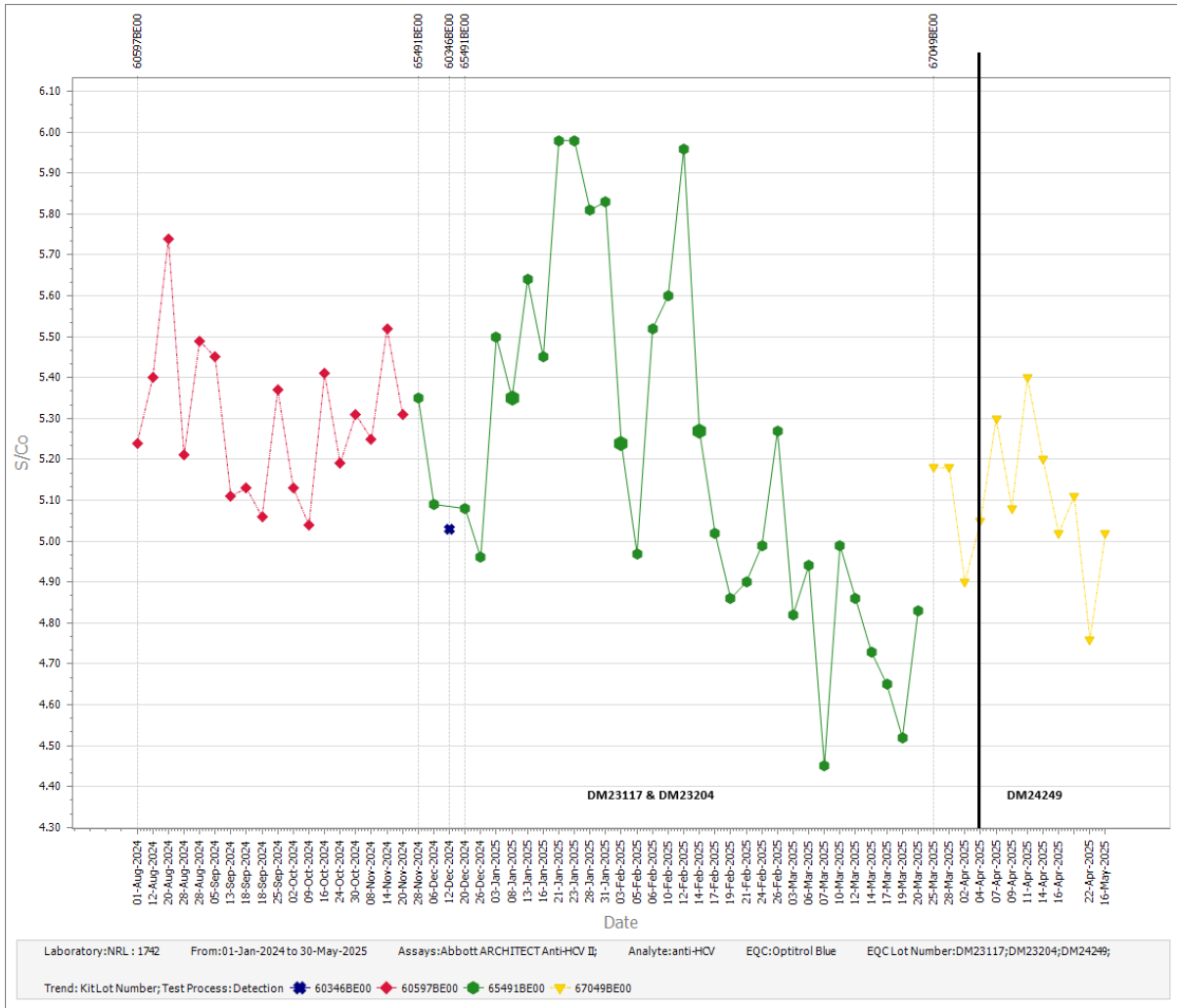


Figure 51- Participant 1742 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

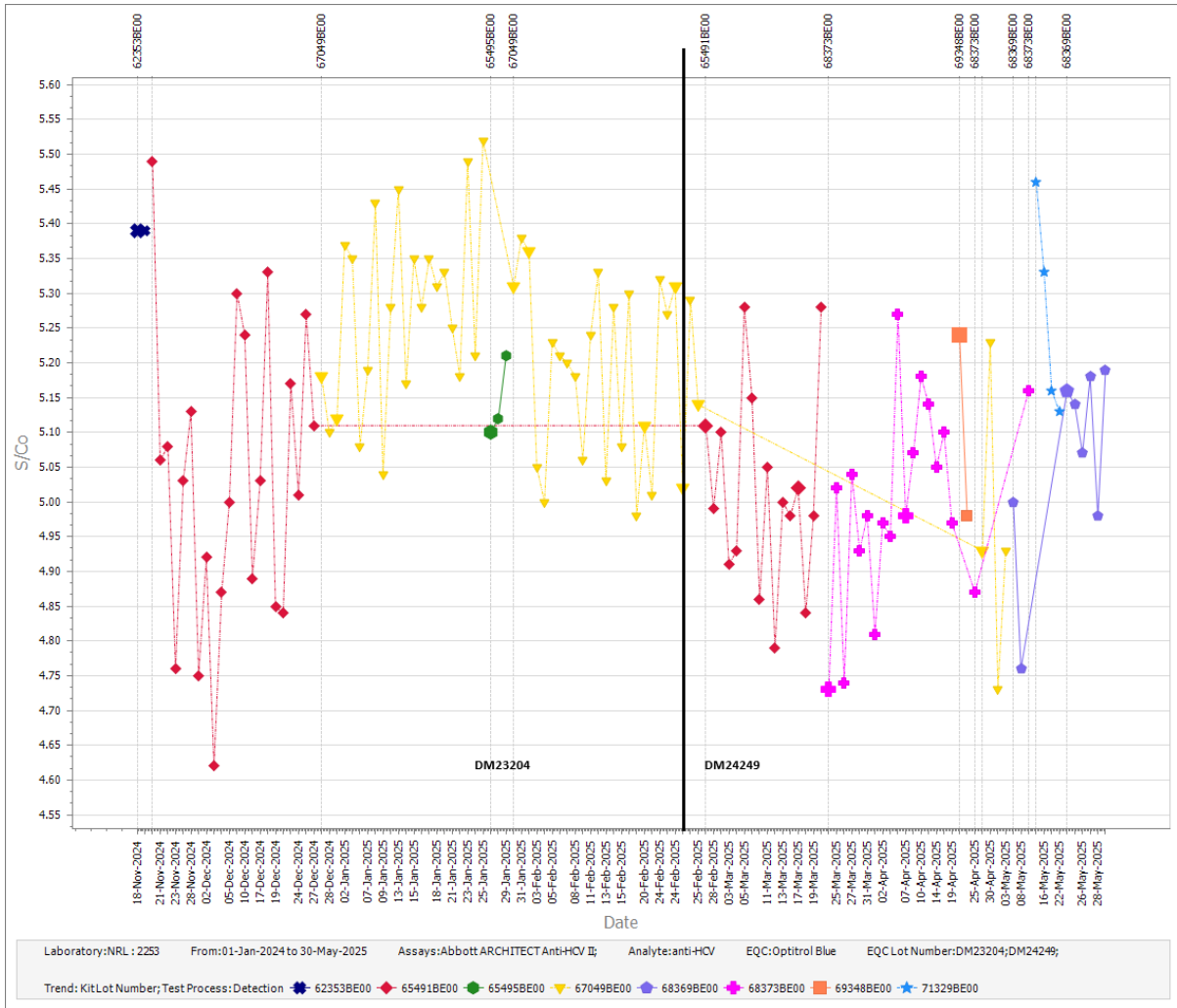


Figure 52- Participant 2253 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

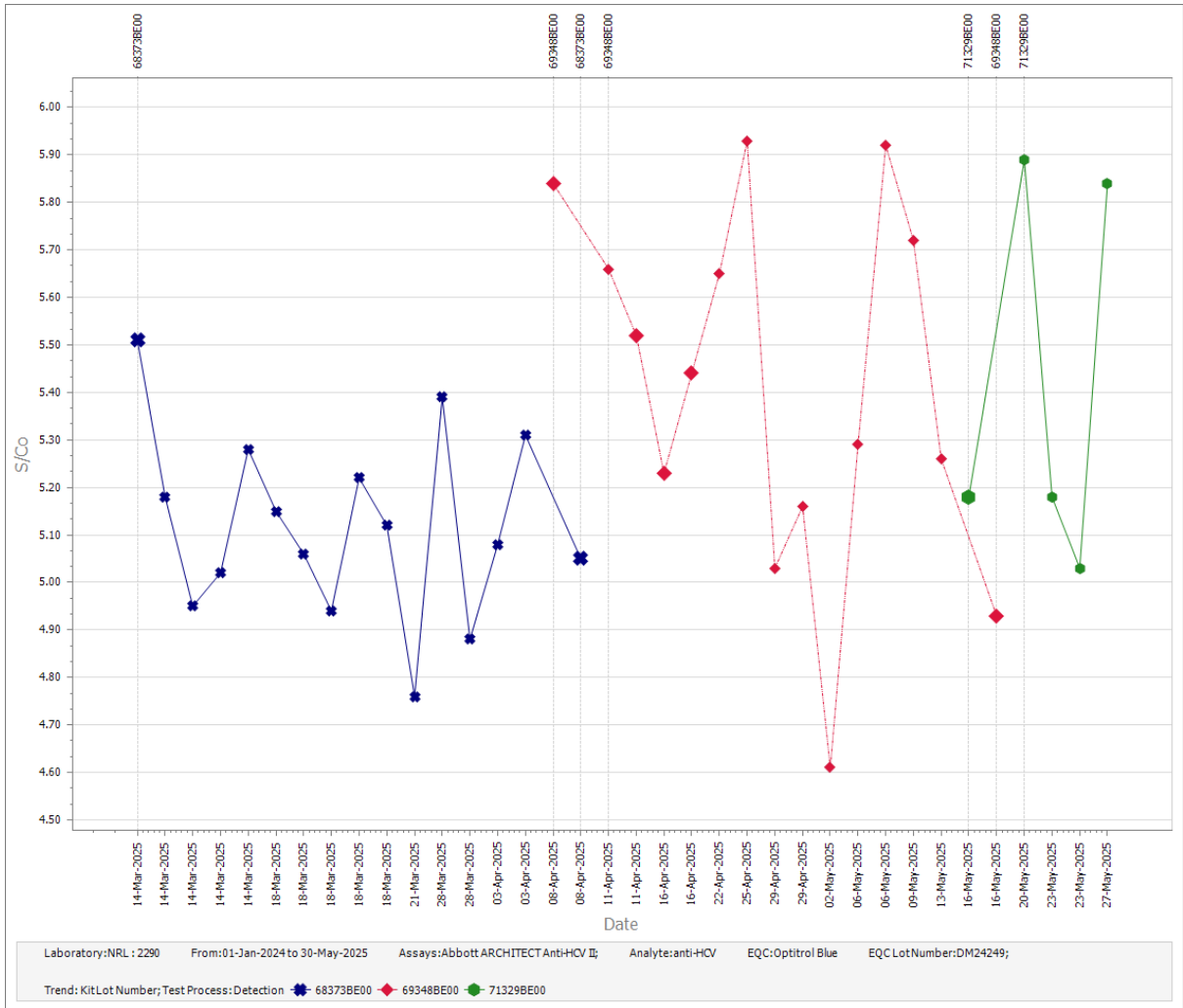


Figure 53- Participant 2290 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

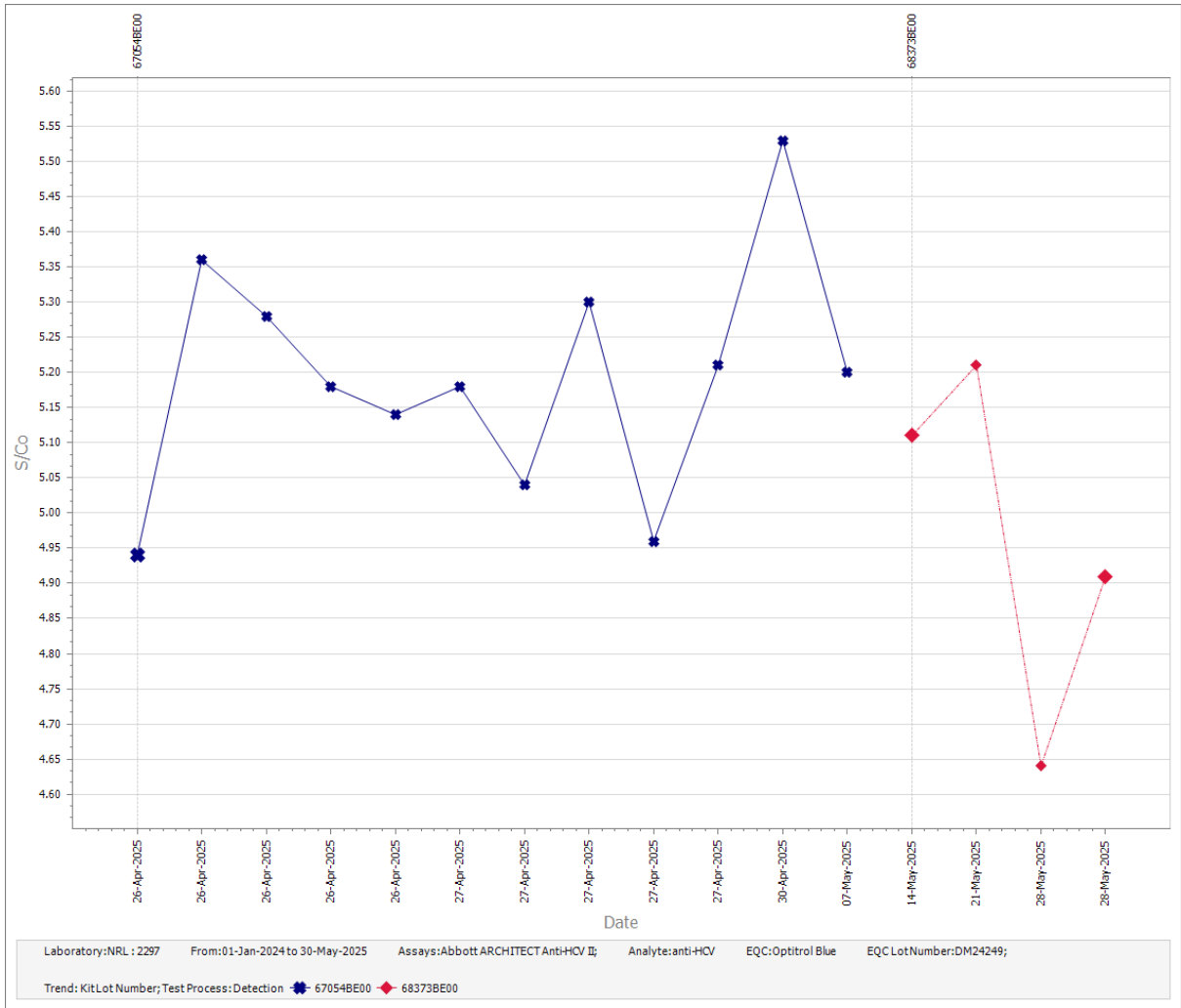


Figure 54- Participant 2297 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

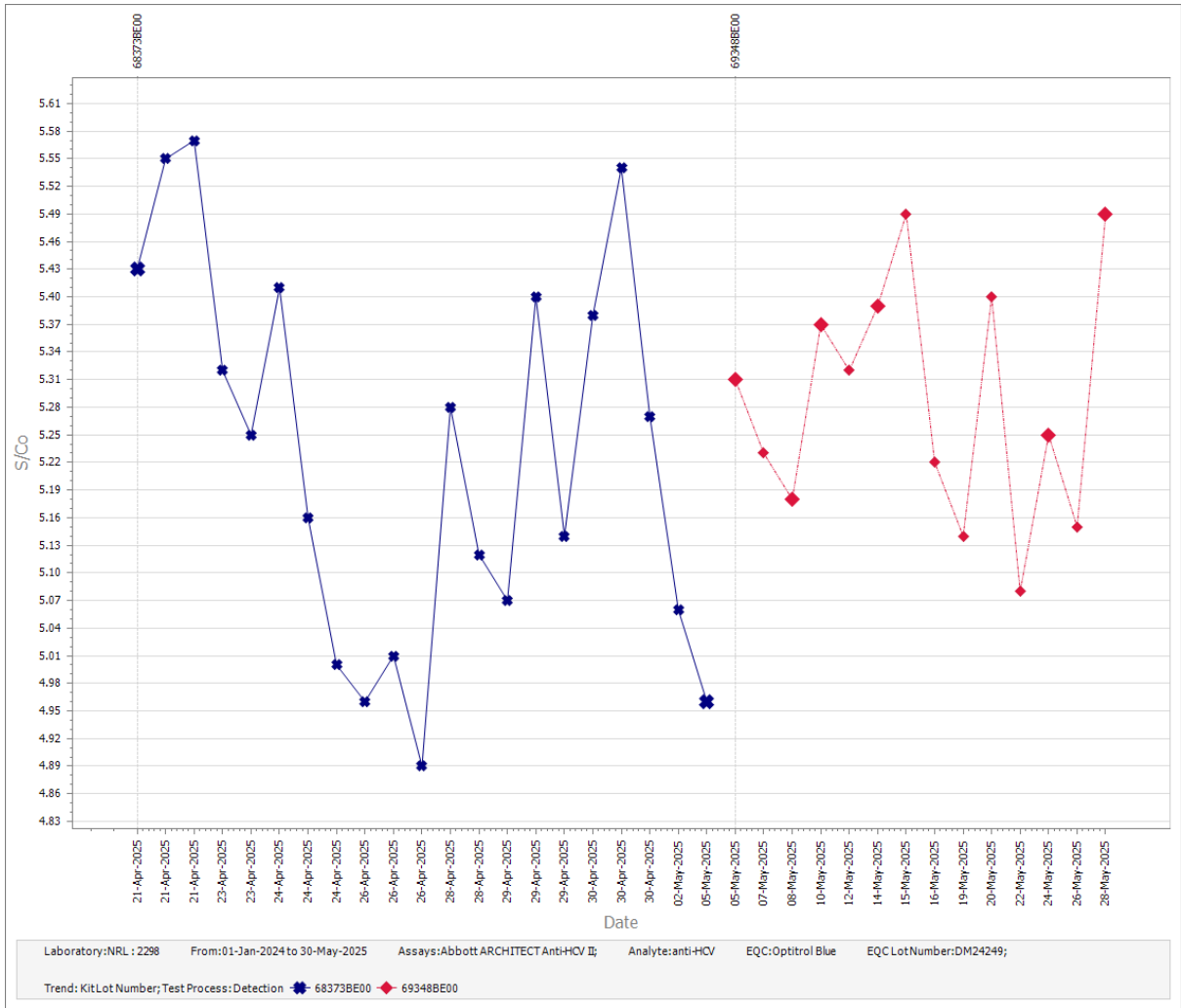


Figure 55- Participant 2298 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue.

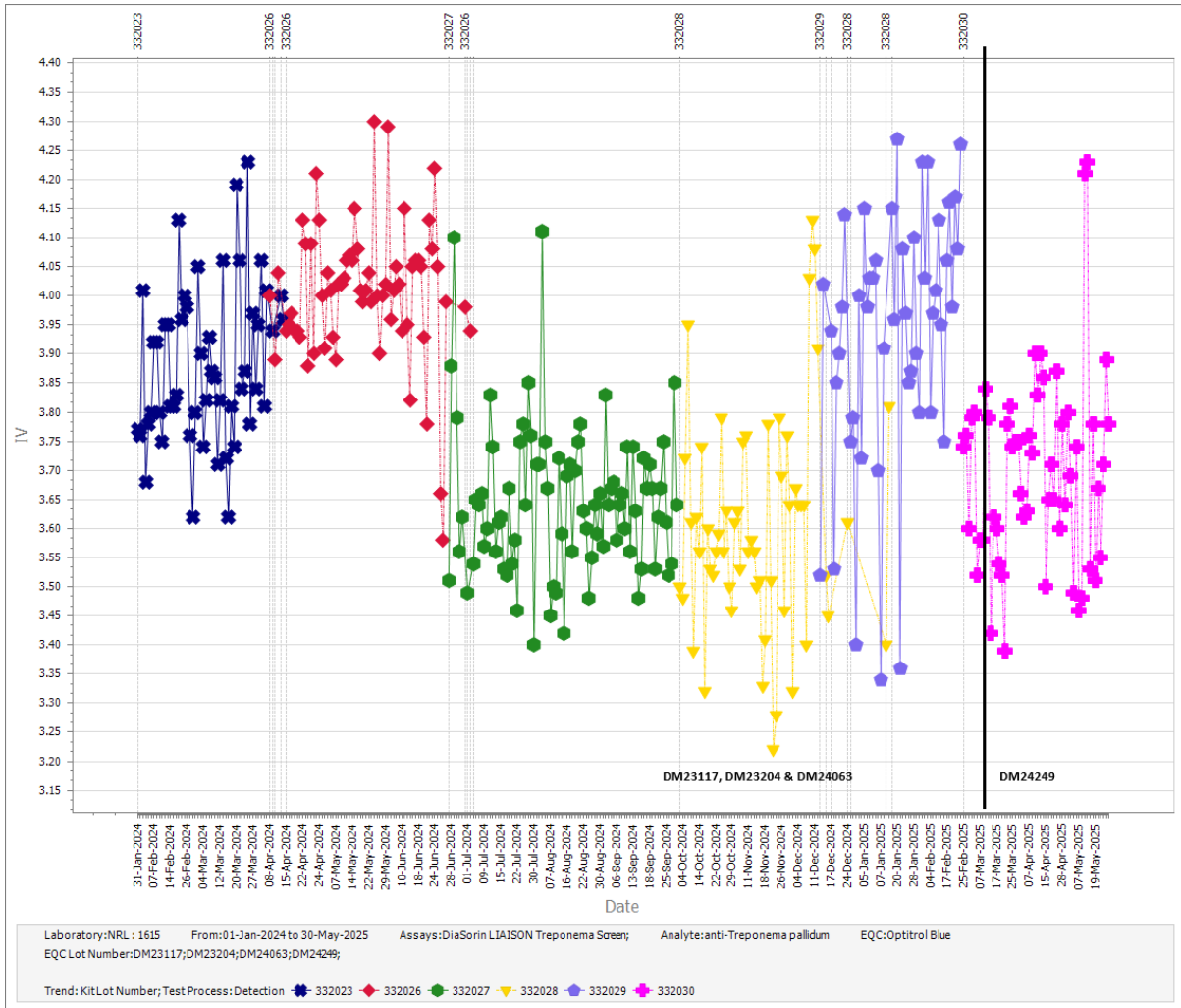


Figure 56 - Participant 1615 data reported on the DiaSorin LIAISON Treponema Screen assay for Optitrol Blue.

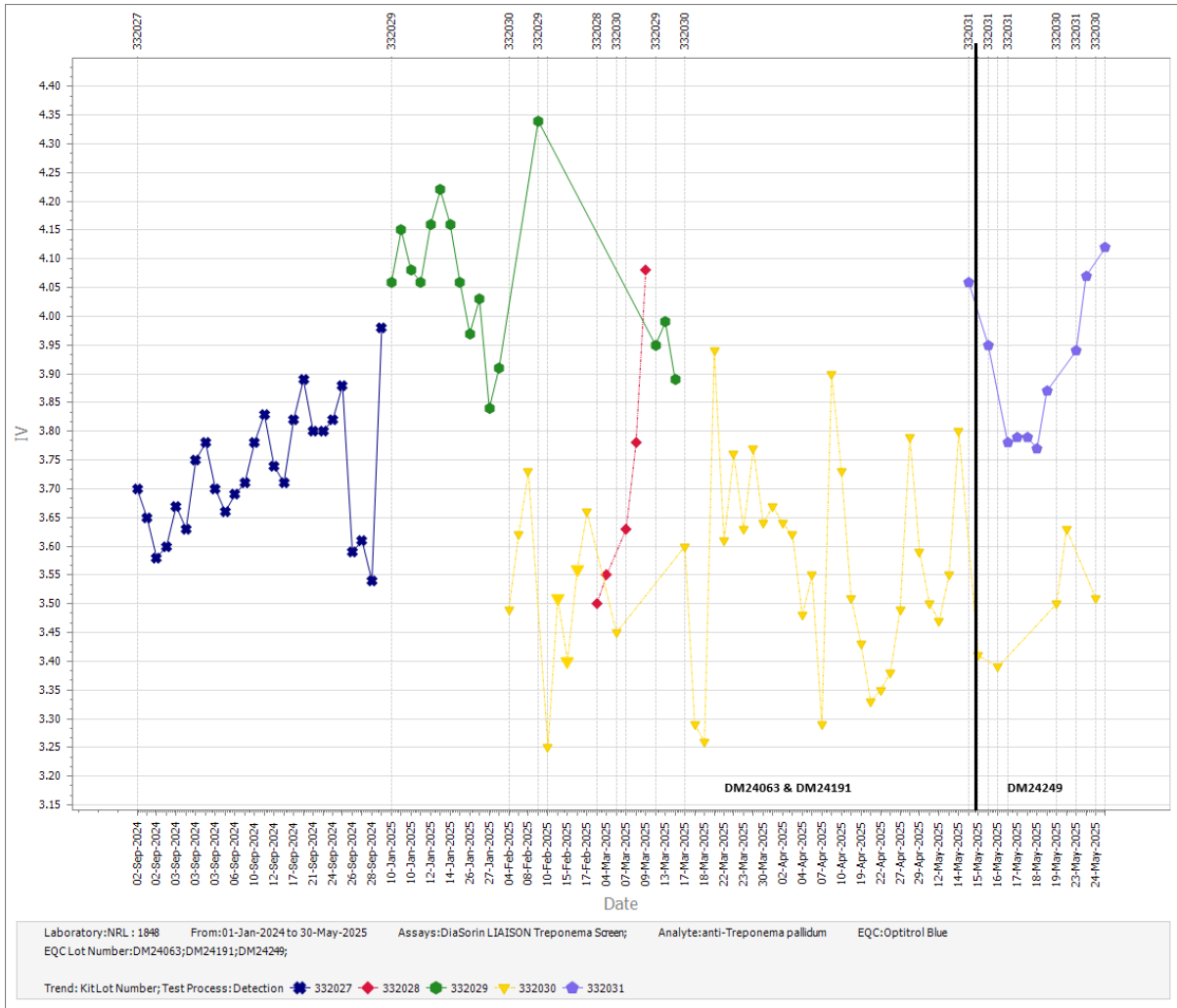


Figure 57 - Participant 1848 data reported on the DiaSorin LIAISON Treponema Screen assay for Optitrol Blue.

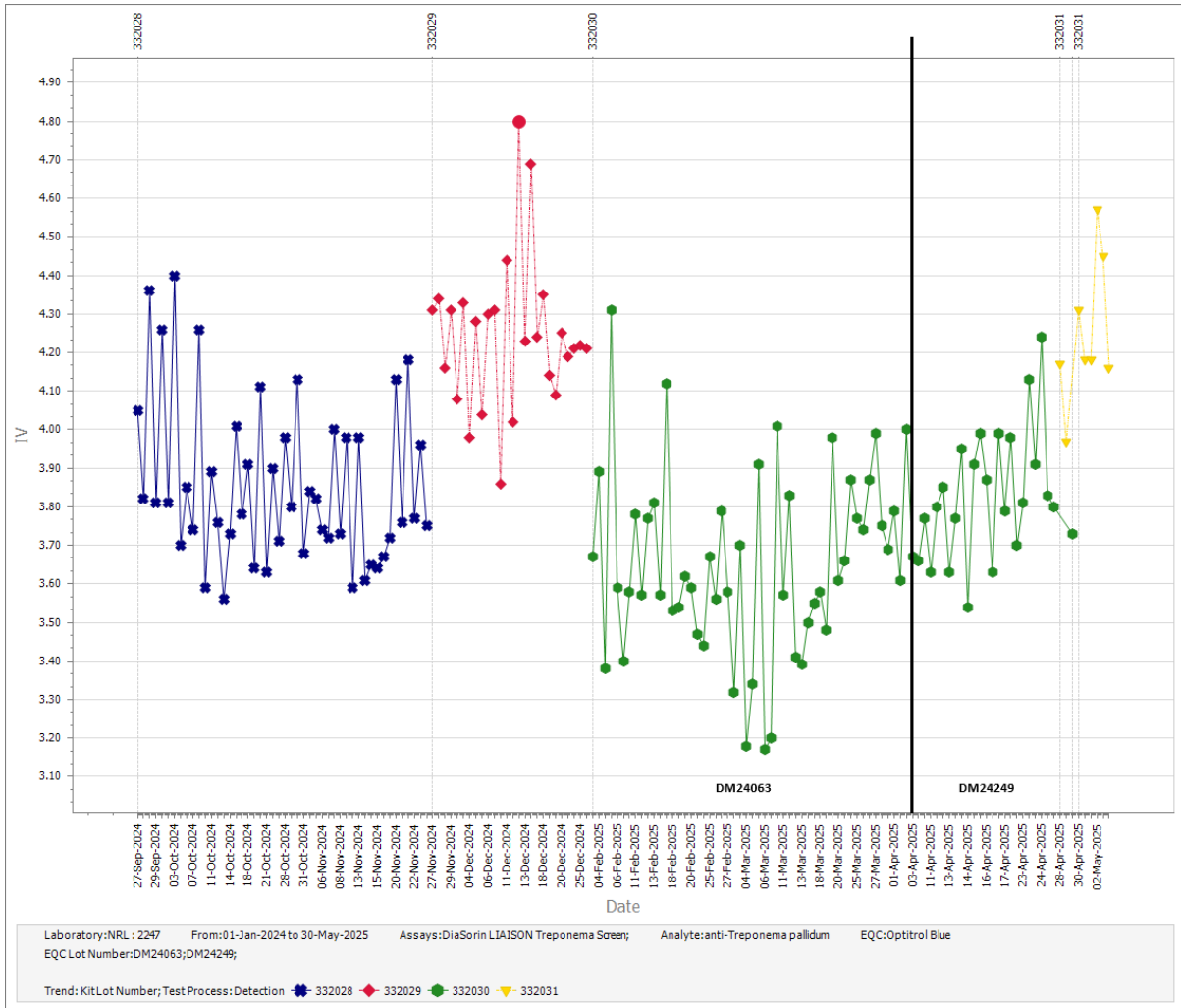


Figure 58 - Participant 2247 data reported on the DiaSorin LIAISON Treponema Screen assay for Optitrol Blue.

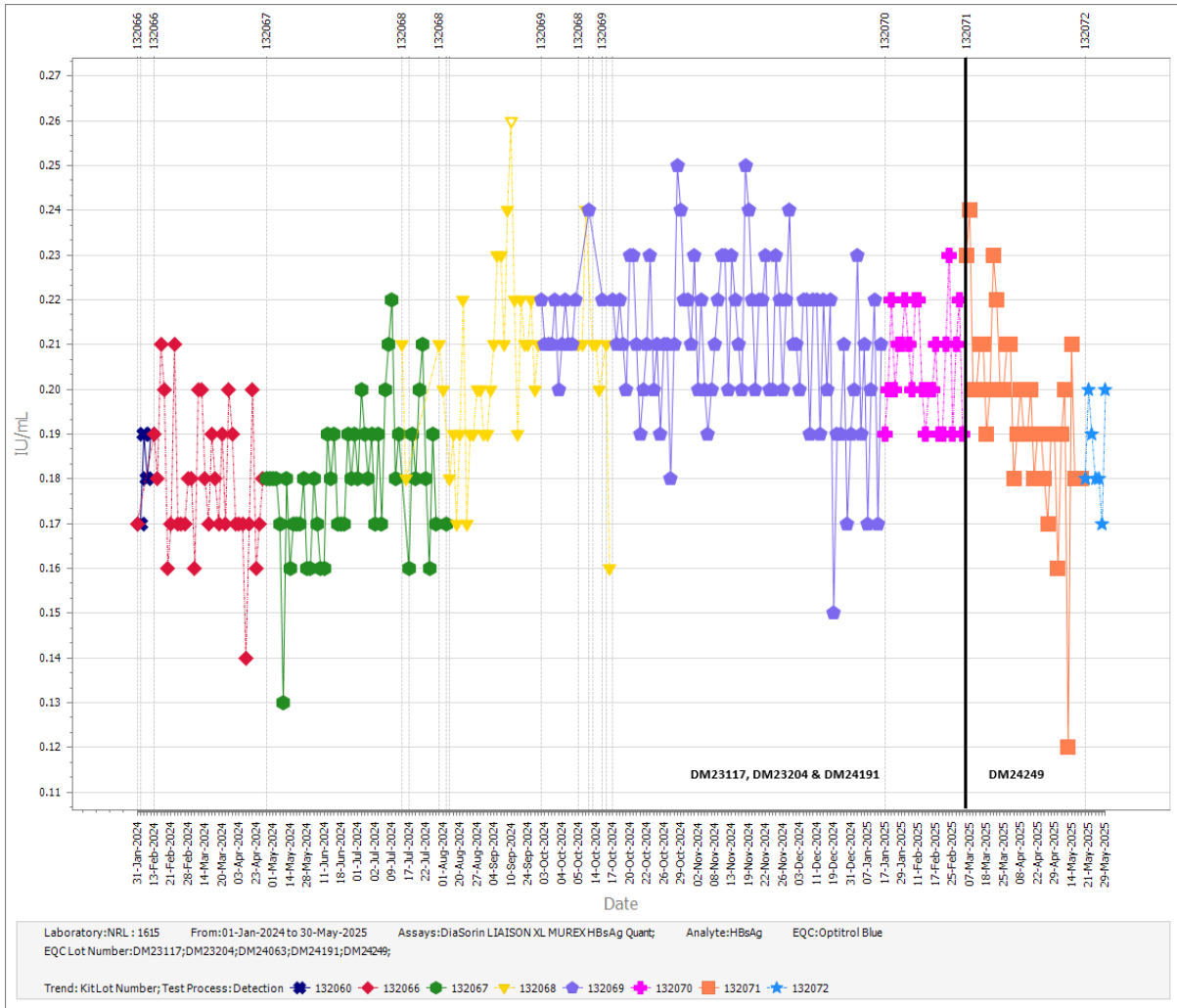


Figure 59 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue.

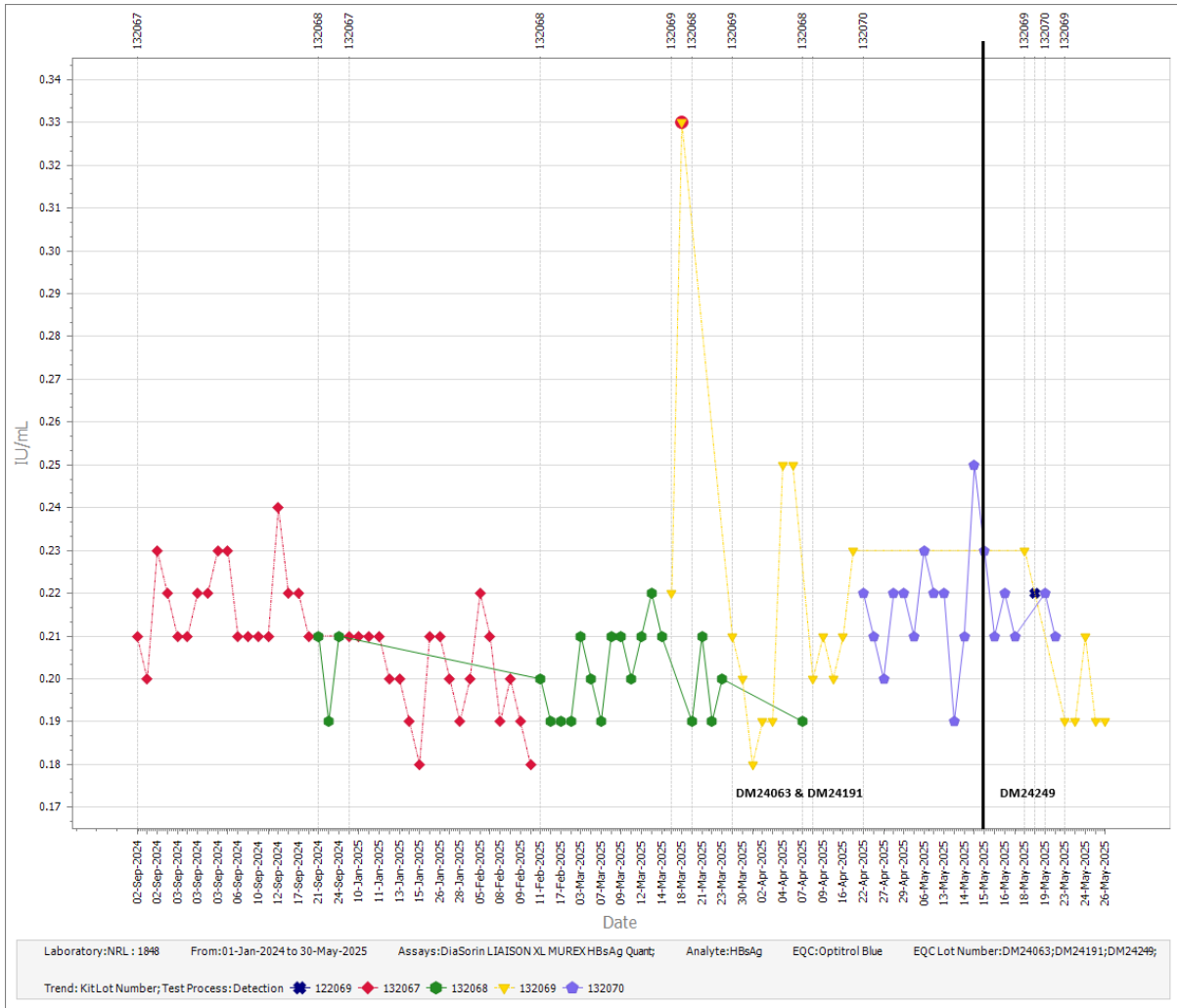


Figure 60 - Participant 1848 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue.

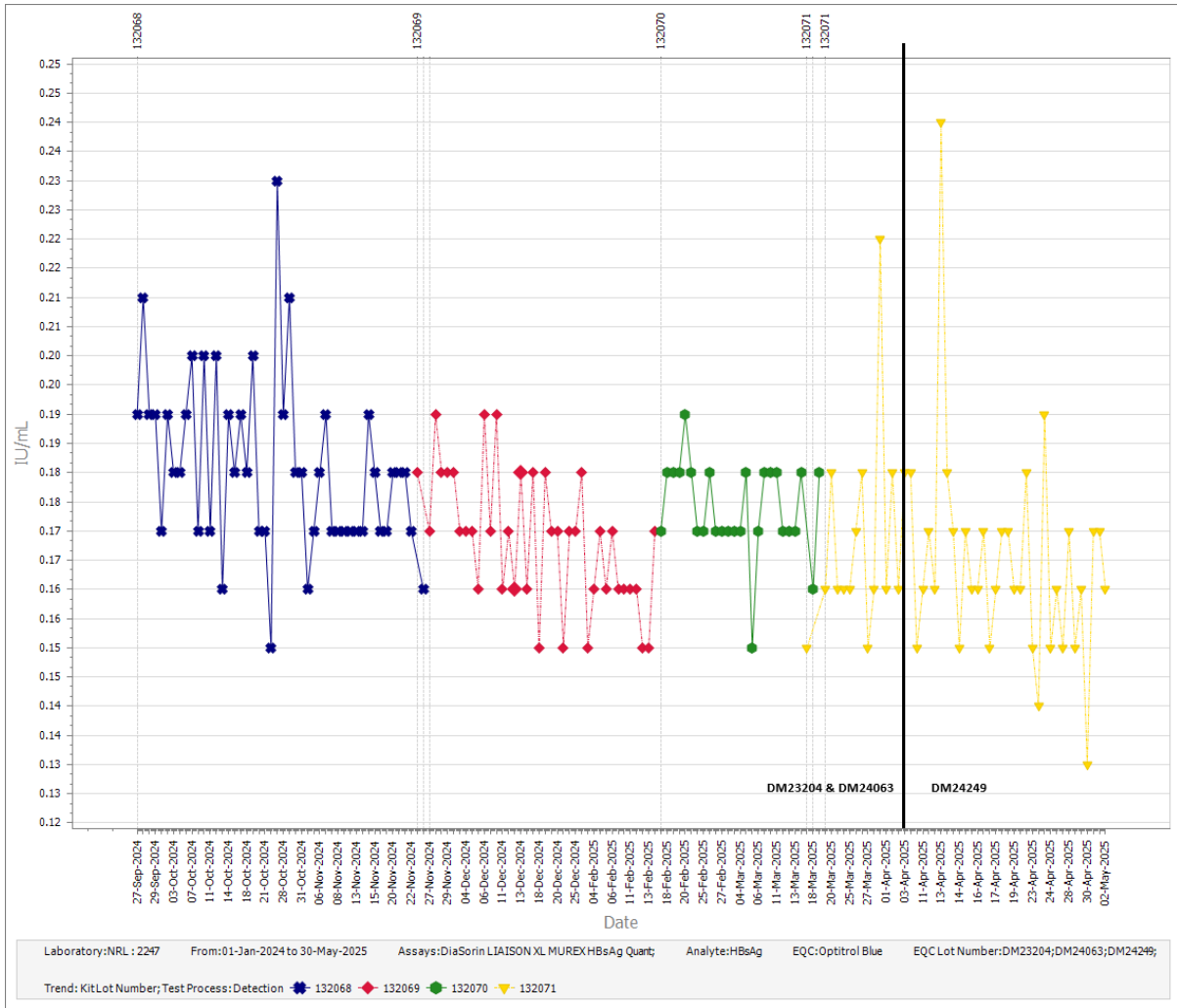


Figure 61 - Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HBSAg Quant assay for Optitrol Blue.

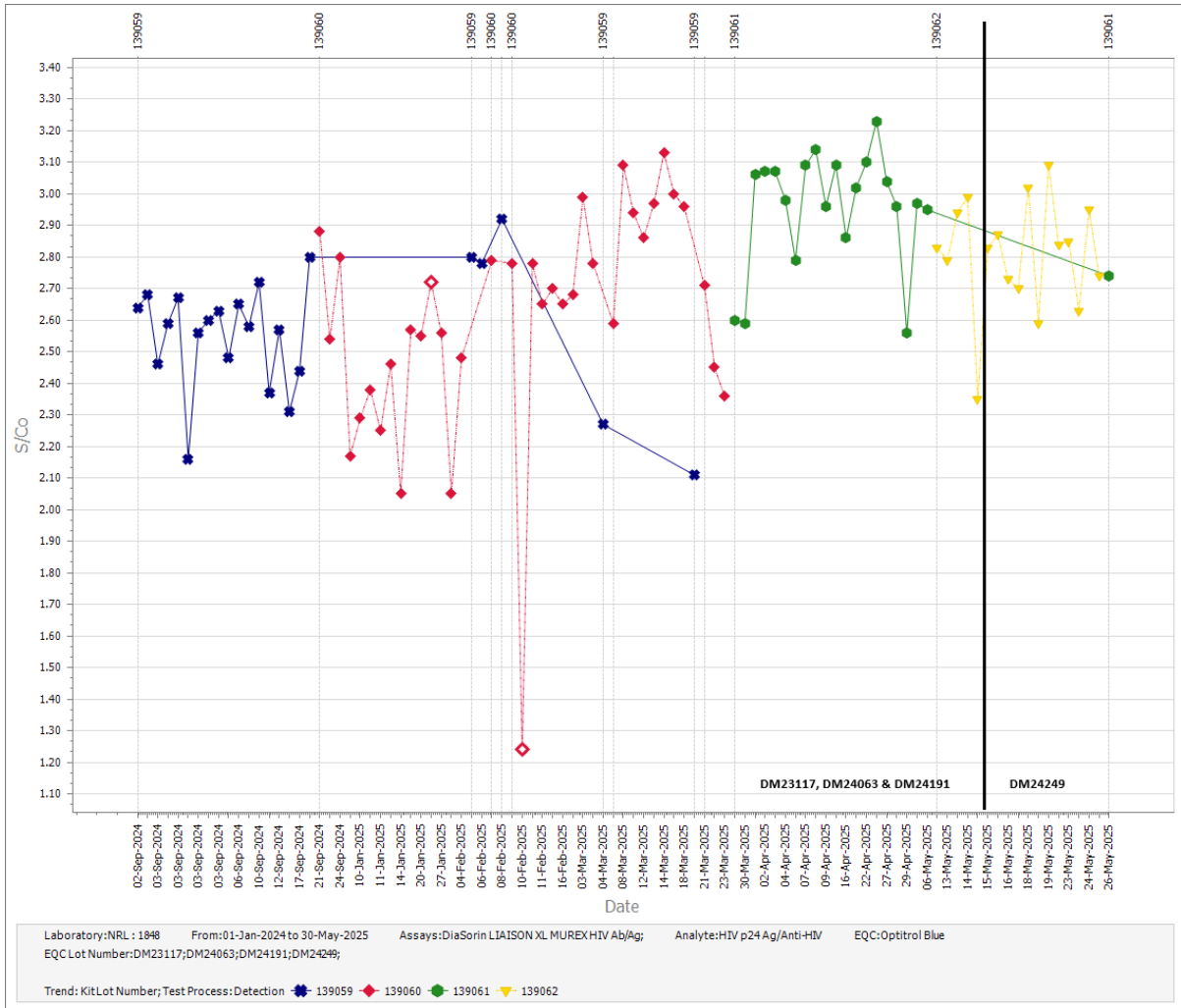


Figure 62 - Participant 1848 data reported on the DiaSorin LIAISON XL MUREX HIV Ab/Ag assay for Optitrol Blue.

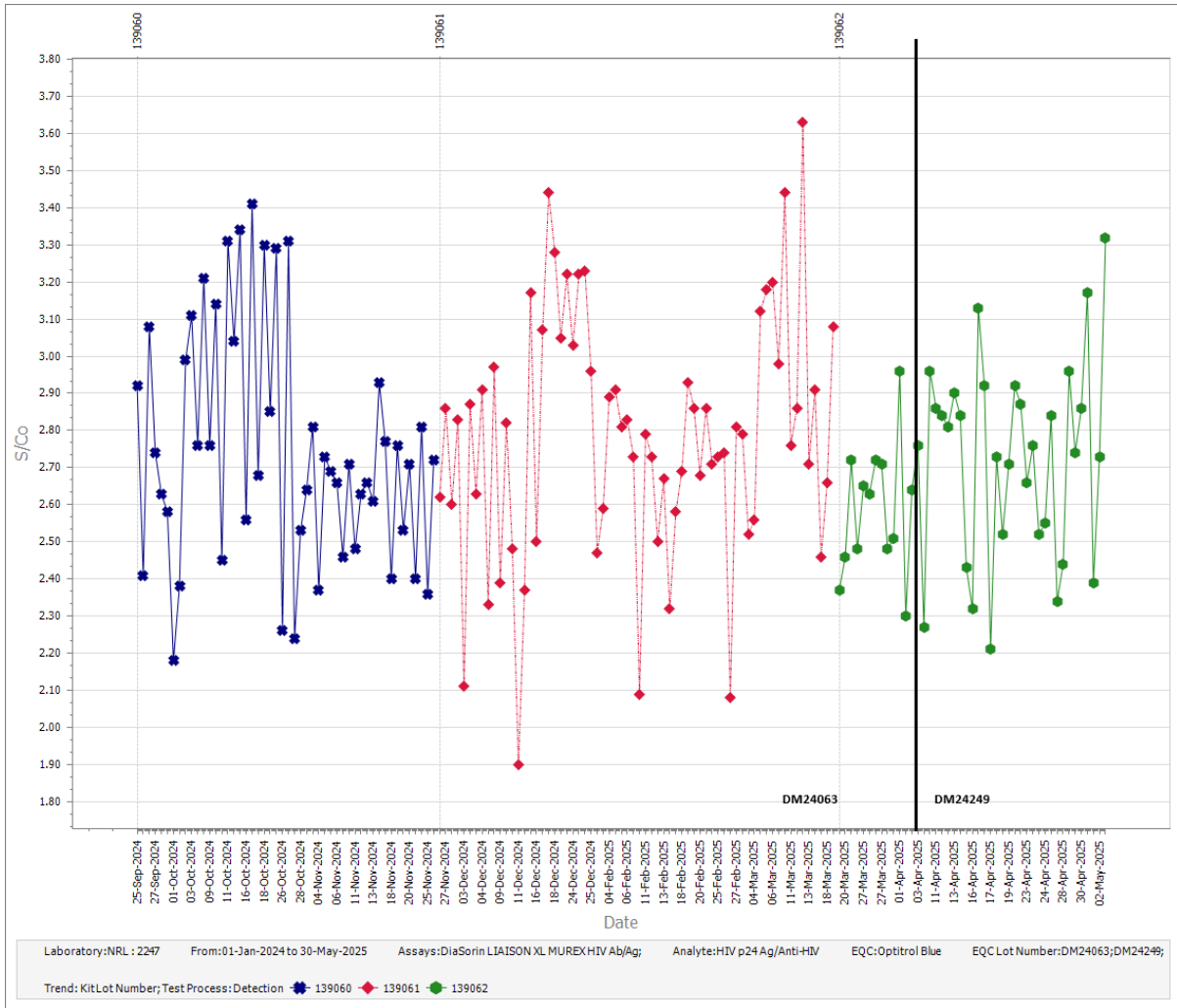


Figure 63 - Participant 2247 data reported on the DiaSorin LIAISON XL MUREX HIV Ab/Ag assay for Optitrol Blue.

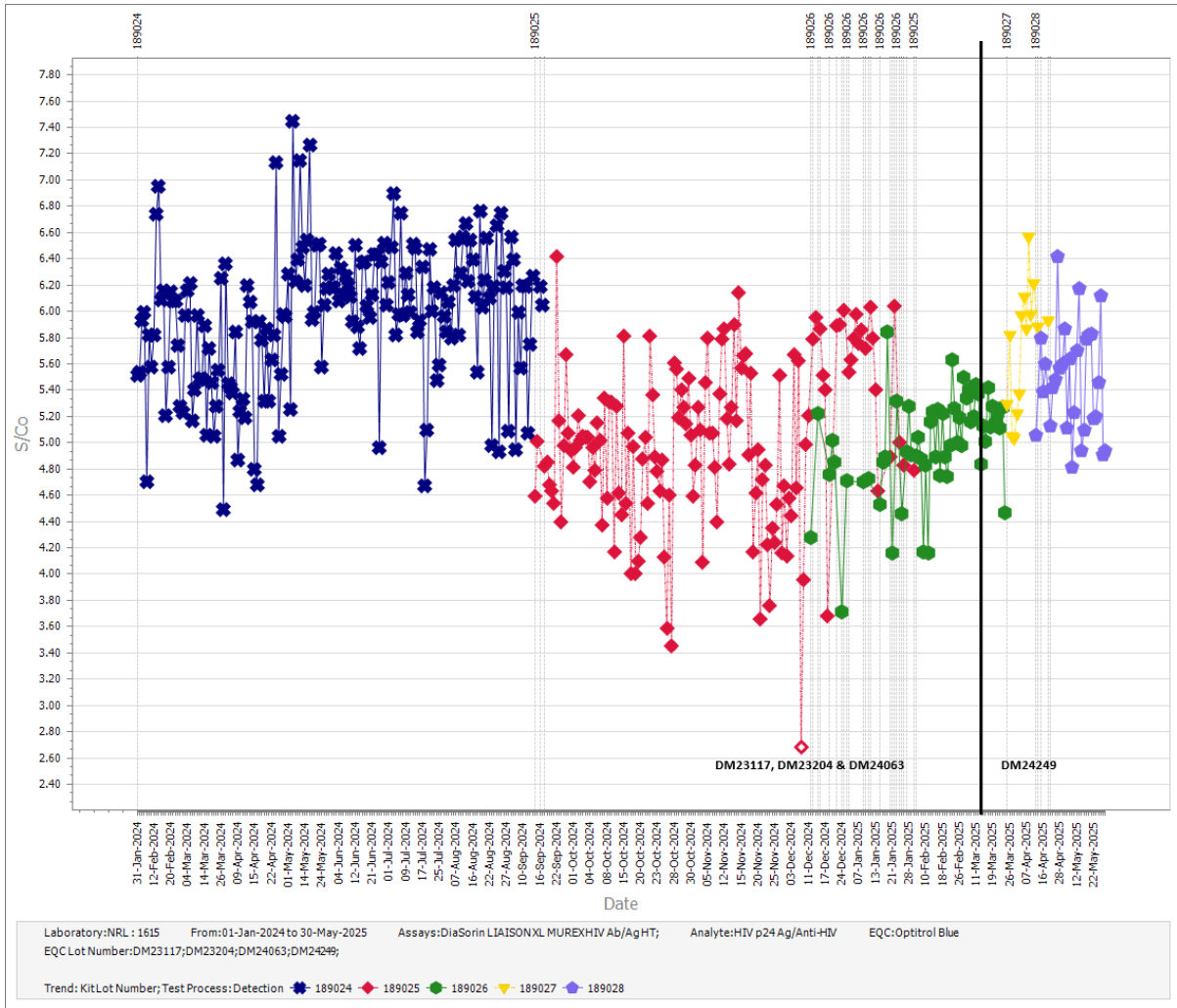


Figure 64 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX HIV Ab/Ag HT assay for Optitrol Blue.

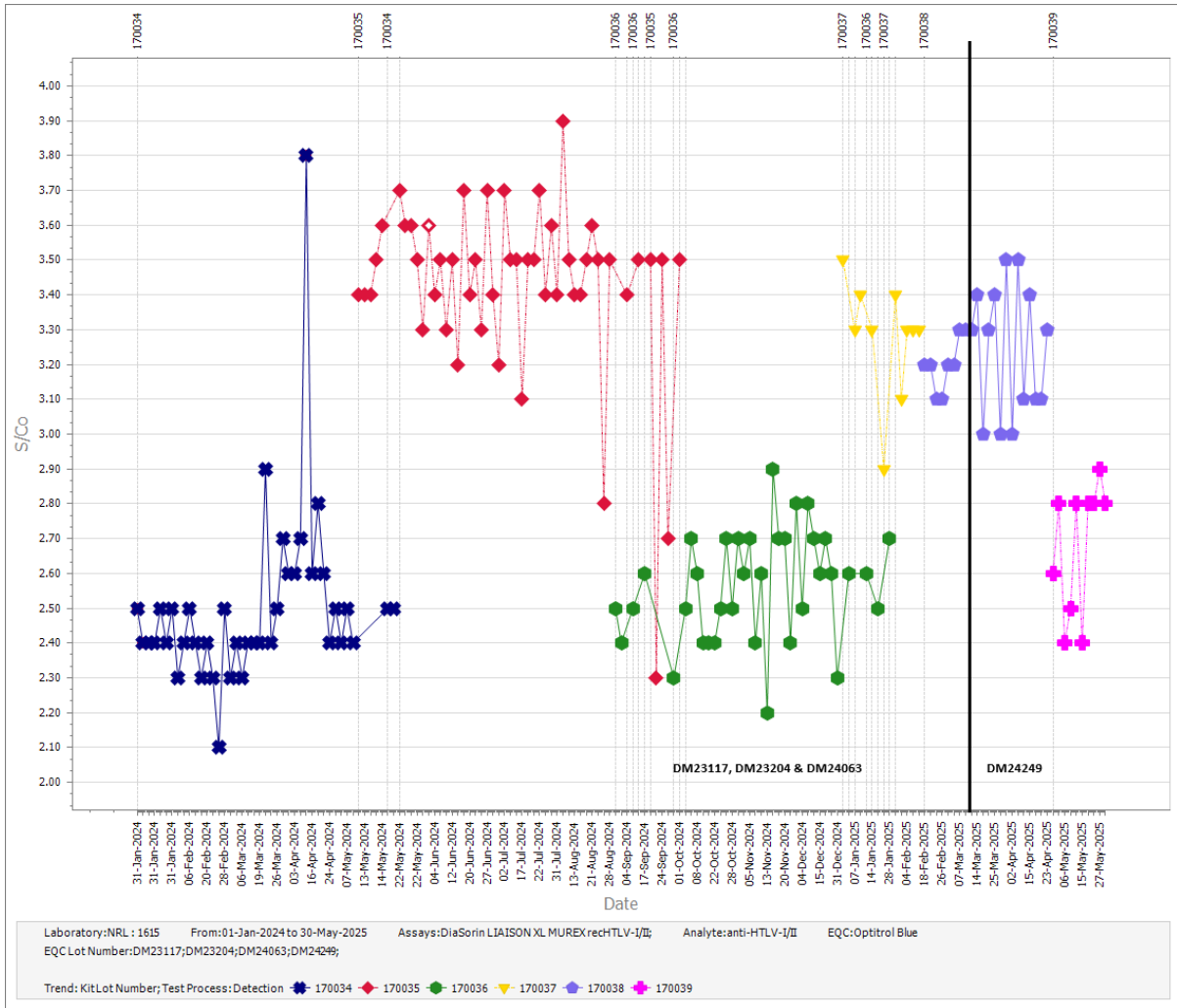


Figure 65 - Participant 1615 data reported on the DiaSorin LIAISON XL MUREX rec HTLV-I-II assay for Optitrol Blue.