

QC Services Investigation: PMM-QC-2434

CONTENTS

INTRODUCTION	3
FINDINGS	3
DISCUSSION.....	6
RECOMMENDATIONS.....	8
APPENDIX I.....	9

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INTRODUCTION

NRL was contacted by the Peruvian Distributor regarding an observed progressive decrease in S/Co value when testing Optitrol Blue DM23117 on the Abbott Alinity i HBsAg Qualitative II assay (Participant 1891) and on the Abbott ARCHITECT HBsAg Qualitative II assay (Participant 2233). All data available reported to EDCNet for HBsAg assays testing with Optitrol Blue DM23117 were reviewed.

FINDINGS

- Figure 1- Participant 1891 data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 2- Participant 1891 data reported on the Abbott Alinity i HBsAg Qualitative II assay for the Abbott positive Kit control.
- Figure 3- Comparison chart of data reported by Participant 1891 for Optitrol Blue DM23117 and Abbott Positive Kit control on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 4- Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by participant, for reagent lots in use by Participant 1891.
- Figure 5- Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 1891.
- Figure 6- Peer group data and mean S/Co values reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 1891.
- Figure 7- Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for all reagent lots in use across the peer group from 01 January through 10 March 2025.
- Figure 8- Participant 8 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.
- Figure 9- Participant 58 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 10- Participant 1380 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 11- Participant 1428 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 12- Participant 1429 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 13- Participant 1431 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 14- Participant 1562 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 15- Participant 1566 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 16- Participant 1614 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 17- Participant 1620 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 18- Participant 1666 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 19- Participant 1689 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 20- Participant 1732 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 21- Participant 1744 data reported on the Abbott Alinity i HBsAg Qualitative II for

Optitrol Blue DM23117

- Figure 22- Participant 1747 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 23- Participant 1748 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 24 Participant 1750 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 25- Participant 1753 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 26- Participant 1860 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 27- Participant 1870 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 28- Participant 1892 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 29- Participant 1945 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117
- Figure 30- Participant 1891 data reported on the Abbott Alinity i Anti-HBc II assay for Optitrol Blue DM23117.
- Figure 31- Participant 1891 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue DM23117.
- Figure 32- Participant 1891 data reported on the Abbott Alinity i HIV Ag/Ab Combo assay for Optitrol Blue DM23117.
- Figure 33- Participant 1891 data reported on the Abbott Alinity i rHTLV-I-II Combo assay for Optitrol Blue DM23117.
- Figure 34- Participant 1891 data reported on the Abbott Alinity i Syphilis TP assay for Optitrol Blue DM23117.
- Figure 35- Participant 2233 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 36- Participant 2233 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for the Abbott positive Kit control.
- Figure 37- Comparison chart of data reported by Participant 2233 for Optitrol Blue DM23117 and Abbott Positive Kit control on the Abbott ARCHITECT HBsAg Qualitative II assay.
- Figure 38- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by participant, for reagent lots in use by Participant 2233.
- Figure 39- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 2233.
- Figure 40- Peer group data and mean S/Co values reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 2233.
- Figure 41- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for all reagent lots in use across the peer group from 01 January through 10 March 2025.
- Figure 42- Participant 8 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 43- Participant 36 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 44- Participant 49 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 45-Participant 58 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 46- Participant 66 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

- Figure 47- Participant 128 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 48- Participant 220 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 49- Participant 365 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 50- Participant 1429 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 51- Participant 1432 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 52- Participant 1737 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 53- Participant 1742 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 54- Participant 1749 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 55- Participant 1754 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 56- Participant 1858 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 57- Participant 1888 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 58- Participant 1890 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 59- Participant 1891 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 60- Participant 1894 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 61- Participant 1939 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 62- Participant 1944 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 63- Participant 1947 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 64- Participant 1973 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 65- Participant 1990 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 66- Participant 1997 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 67- Participant 2176 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 68- Participant 2177 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 69- Participant 2248 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 70- Participant 2271 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.
- Figure 72- Participant 2233 data reported on the Abbott ARCHITECT Anti-HBc II assay for Optitrol Blue DM23117.
- Figure 72- Participant 2233 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue DM23117.
- Figure 73-Participant 2233 data reported on the Abbott ARCHITECT HIV Ag/Ab Combo assay

for Optitrol Blue DM23117.

- Figure 74- Participant 2233 data reported on the Abbott ARCHITECT rHTLV-I-II assay for Optitrol Blue DM23117.
- Figure 75- Participant 2233 data reported on the Abbott ARCHITECT Syphilis TP assay for Optitrol Blue DM23117.
- Figure 76- Peer group data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117 by participant.
- Figure 77- Peer group data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117 by reagent lot.
- Figure 78- Participant 57 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.
- Figure 79- Participant 1353 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.
- Figure 80- Participant 1356 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.
- Figure 81- Abbott Positive Kit control data reported by Participant 58 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 82- Abbott Positive Kit control data reported by Participant 1747 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 83- Abbott Positive Kit control data reported by Participant 1748 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 84- Abbott Positive Kit control data reported by Participant 1753 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 85- Abbott Positive Kit control data reported by Participant 1860 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 86- Abbott Positive Kit control data reported by Participant 1945 on the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 87- Abbott Positive Kit control data reported by Participant 1429 on the Abbott ARCHITECT HBsAg Qualitative II assay.
- Figure 88- Abbott Positive Kit control data reported by Participant 1432 on the Abbott ARCHITECT HBsAg Qualitative II assay.
- Figure 89- Abbott Positive Kit control data reported by Participant 1737 on the Abbott ARCHITECT HBsAg Qualitative II assay.
- Figure 90- Abbott Positive Kit control data reported by Participant 1749 on the Abbott ARCHITECT HBsAg Qualitative II assay.
- Figure 91- Abbott Positive Kit control data reported by Participant 1890 on the Abbott ARCHITECT HBsAg Qualitative II assay.

DISCUSSION

Data reported by Participant 1891 for Optitrol Blue DM23117 and Abbott Positive Kit control when testing on the Abbott Alinity i HBsAg Qualitative II assay are illustrated in Figures 1 and 2, respectively. Figure 3 illustrates these data in a single chart for comparison. Six reagent lots were in use, 50362FN00, 54074FN00, 59341FZ00, 61288FZ00, 64236FZ00 and 66206FZ00, for both quality control (QC) products, similar shifts were observed due reagent lot variation and known/expected calibration and/or maintenance events, noted by * on Figure 3. These shifts were observed both within- and between-reagent lot usage for data reported for Optitrol Blue DM23117.

Figures 4, 5 and 6 illustrate Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay testing with Optitrol Blue DM23117 and the six reagent lots in use for Participant 1891.

Figures 5 and 6 illustrate reagent lot variation, noting both a trend down in S/Co values consistent across the peer group and Participant 1891 data reported lower than that of the peer group data and mean S/Co value for all six reagent lots in use. Figure 7 shows peer group data for all reagent lots where Optitrol Blue DM23117 was in use on the Abbott Alinity i HBsAg Qualitative II assay. A trend down in reagent variation was observed.

Figures 8 through 29 show each peer group participant Levy Jennings chart for Optitrol Blue DM23117 reported on the Abbott Alinity i HBsAg Qualitative II assay. A total of 22 participants had reported data across 23 reagent lots. Reagent lot variation and shifts due to calibration or maintenance were observed consistently across the peer group. No evidence of a downward trend specific to Optitrol Blue DM23117 was identified for the peer group.

Figures 30 through 34 show Participant 1891 data reported for Optitrol Blue DM23117 on the Abbott Alinity i Anti-HBc II, Abbott Alinity i Anti-HCV II, Abbott Alinity i HIV Ag/Ab Combo, Abbott Alinity i rHTLV-I/II and Abbott Alinity i Syphilis TP assays. Expected reagent lot variation and shifts due to calibration or maintenance were observed for each assay. No evidence of a downward trend specific to Optitrol Blue DM23117 was identified.

Data reported by Participant 2233 for Optitrol Blue DM23117 and Abbott Positive Kit control testing with the Abbott ARCHITECT HBsAg Qualitative II assay are illustrated in Figures 35, 36 and 37 respectively. Figure 37 illustrates these data in a single chart for comparison. Five reagent lots were in use, 59411FZ00, 62186FZ00, 64137FZ00, 66091FZ00 and 68095FZ00, for both Quality Control (QC) products, similar shifts observed due reagent lot variation and known or expected calibration and / or maintenance events, noted by * on Figure 37. These shifts were observed both within and between reagent lot usage for data reported for Optitrol Blue DM23117.

Figures 38 through 41 illustrate Peer group data reported for Optitrol Blue DM23117 testing with the Abbott ARCHITECT HBsAg Qualitative II assay and the five reagent lots in use for Participant 2233. Figures 37 and 38 illustrate reagent lot variation, noting both a trend down in S/Co values consistent across the peer group and Participant 1891 data reported lower than that of the peer group data and mean S/Co value for all three of the six reagent lots in use. For two reagent lots, 66091FZ00 and 68095FZ00, where Participant 2233 reported a mean S/Co value equal to or higher than the peer group a maximum of three data points were reported.

Figures 42 through 70 show each peer group participant Levy Jennings chart for Optitrol Blue DM23117 reported on the Abbott ARCHITECT HBsAg Qualitative. A total of 28 participants had reported data across 52 reagent lots. Reagent lot variation and shifts due to calibration or maintenance were observed consistently across the peer group. No evidence of a downward trend specific to Optitrol Blue DM23117 was identified for the peer group.

Figures 71 through 75 show Participant 1891 data reported for Optitrol Blue DM23117 when tested with the Abbott ARCHITECT Anti-HBc II, Abbott ARCHITECT Anti-HCV II, Abbott ARCHITECT HIV Ag/Ab Combo, Abbott ARCHITECT rHTLV-I/II and Abbott ARCHITECT Syphilis TP assays. Expected reagent lot variation and shifts due to calibration or maintenance were observed for each assay. No evidence of a downward trend specific to Optitrol Blue DM23117 was identified.

Figures 76 and 77 show peer group data reported to EDCNet for Optitrol Blue DM23117 on the DiaSorin LIAISON XL MUREX HBsAg Quant assay. Figures 78, 79 and 80 show individual

participant data reported to EDCNet for Optitrol Blue DM23117 on the DiaSorin LIAISON XL MUREX HBsAg Quant assay. Minimal reagent lot variation was observed and no evidence of a downward trend specific to Optitrol Blue DM23117 was identified.

Similar observation to the downward trend reported by Participants 1891 and 2233 for each the Abbott Alinity i HBsAg Qualitative II and Abbott ARCHITECT HBsAg Qualitative II assay respectively were observed for Participants 58, 1747, 1748, 1753, 1860 and 1945 (Figures 9, 22, 23, 25, 26 and 29) on the Abbott Alinity i HBsAg Qualitative II assay and for Participants 128, 1429, 1432, 1737, 1749, 1890 and 1939 (Figures 47, 50, 51, 52, 54, 58 and 61) on the Abbott ARCHITECT HBsAg Qualitative II assay. A review of data reported for each of these participants showed shifts due to reagent lot variation and / or scheduled and required calibration and maintenance events. These findings were reflected in the Abbott positive Kit control data reported by each participant where the data shifts and trends observed for the Optitrol Blue DM23117 are observed for the reported Abbott Positive Kit control (Figures 81 through 91). No Abbott positive kit control data were reported by Participants 128 and 1939.

The appearance of a downward trend reported by Participants 1891 and 2233 for each the Abbott Alinity i HBsAg Qualitative II and Abbott ARCHITECT HBsAg Qualitative II assay respectively was also observed for Abbott positive Kit control data from both participants and reflected in peer group data for both the Optitrol Blue DM23117 and Abbott positive kit control samples.

All data findings appear to rule out an overall downward trend specific to or due to the use Optitrol Blue DM23117.

RECOMMENDATIONS

NRL recommends participants record calibration, maintenance and new reagent and quality control sample into EDCNet to aid in data review.

NRL recommends participants report and review assay manufacture kit control data in partnership with Optitrol data.

NRL recommends participants ensure Optitrol products are stored and used as per the product IFU.

NRL recommends participants ensure all assay components, such as reagent kits, are stored and used as per the product IFU.

APPENDIX I

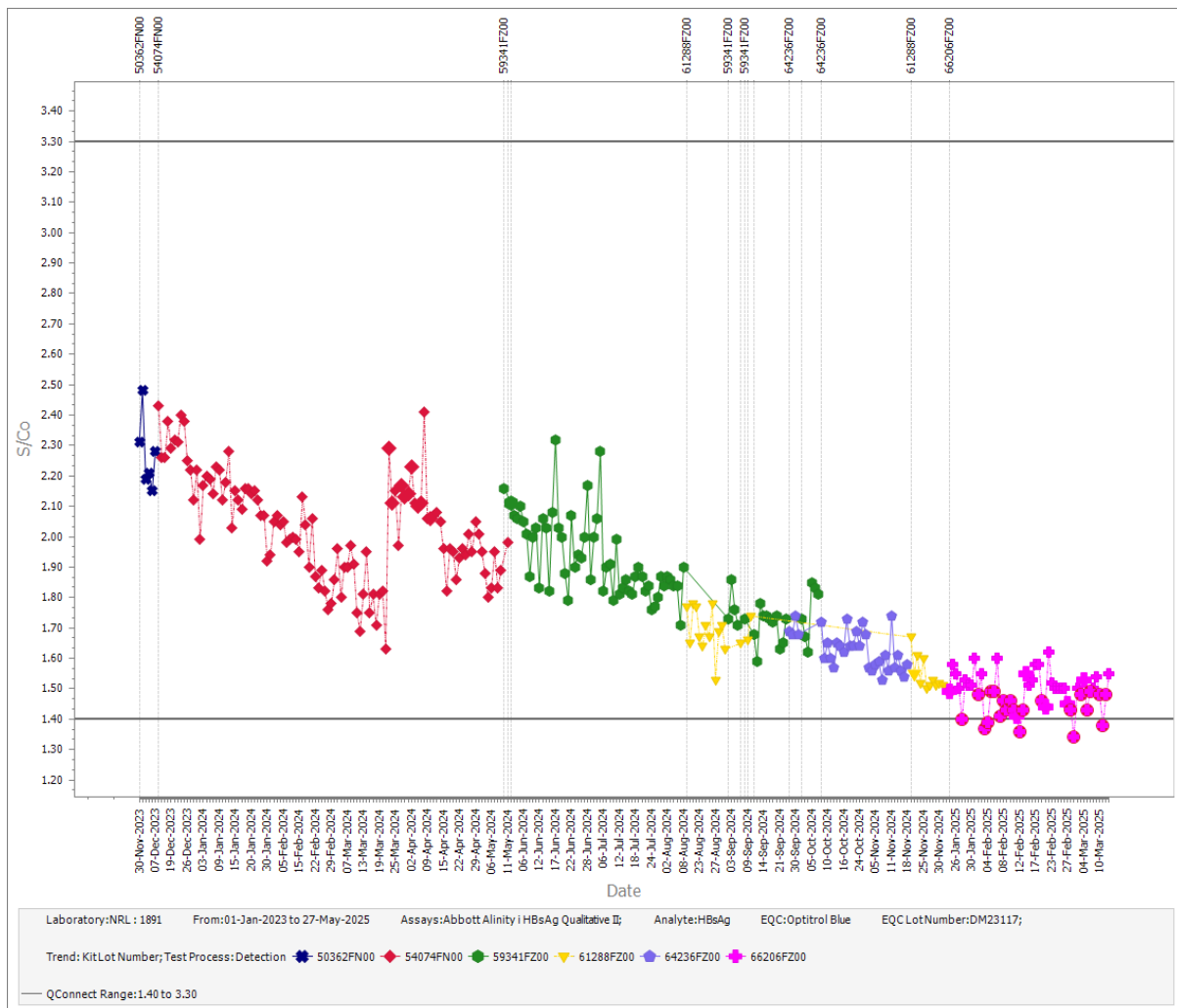


Figure 1- Participant 1891 data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117.

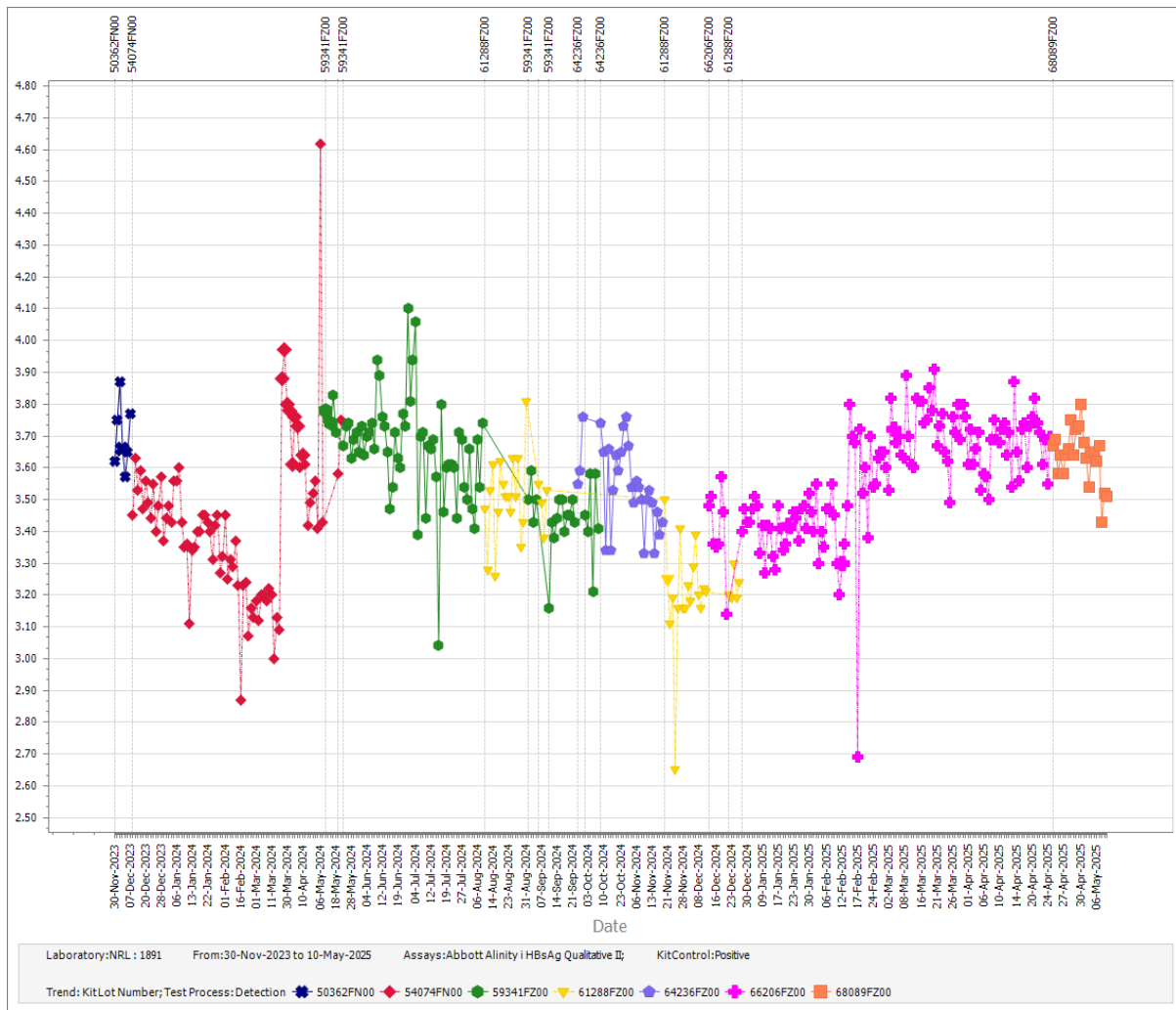


Figure 2- Participant 1891 data reported on the Abbott Alinity i HBsAg Qualitative II assay for the Abbott positive Kit control.

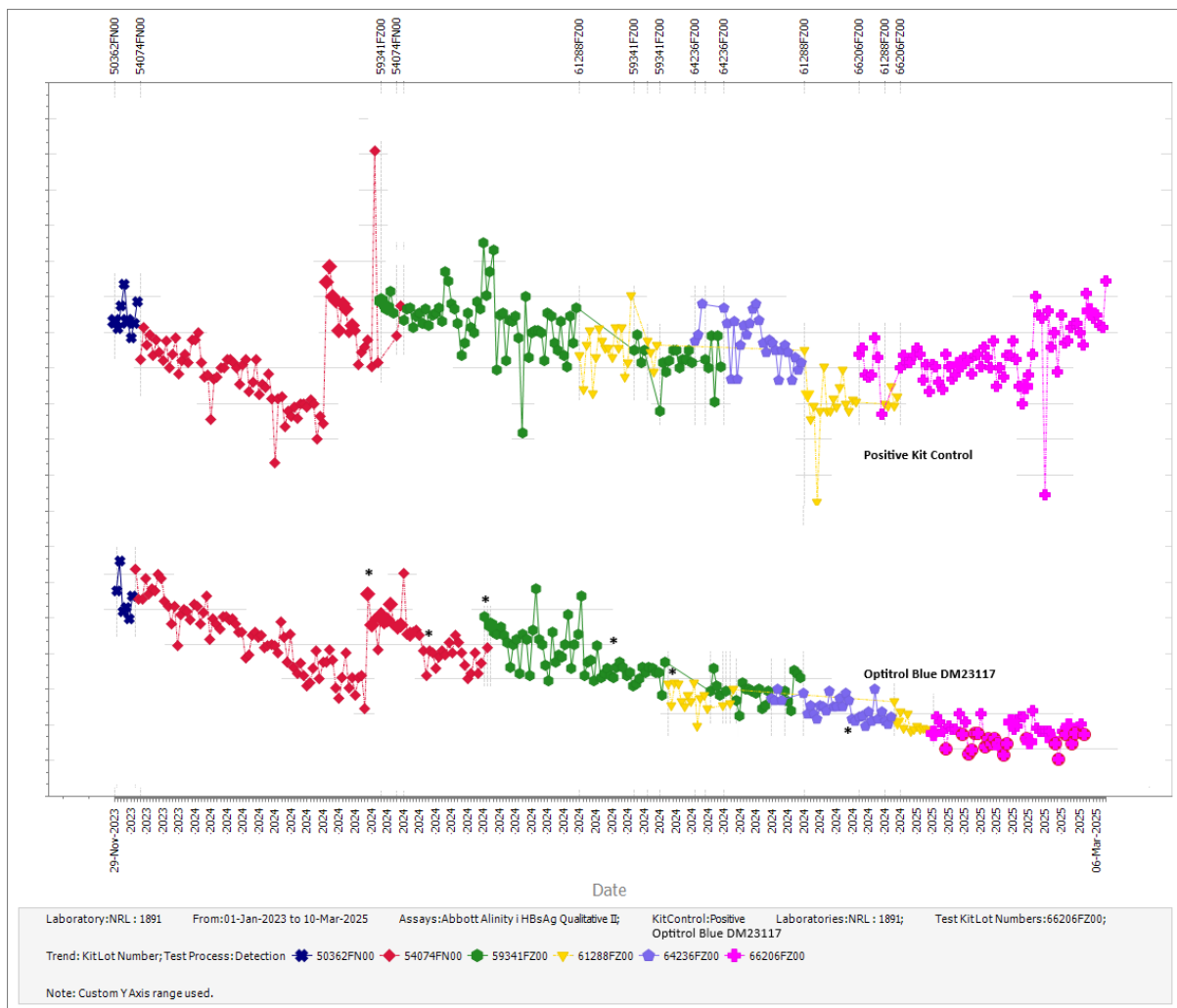


Figure 3- Comparison chart of data reported by Participant 1891 for Optitrol Blue DM23117 and Abbott Positive Kit control on the Abbott Alinity i HBsAg Qualitative II assay.

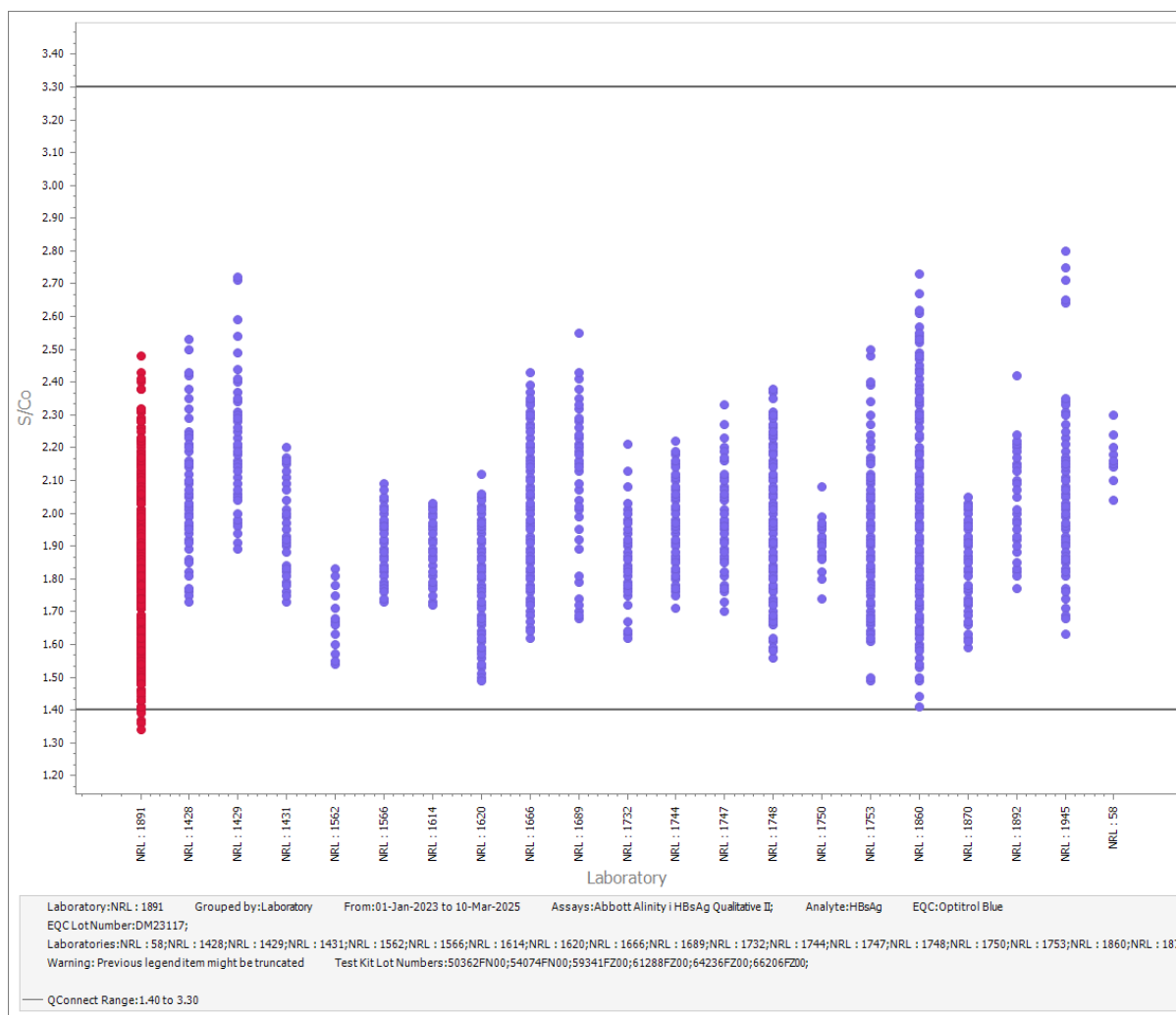


Figure 4- Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by participant, for reagent lots in use by Participant 1891.

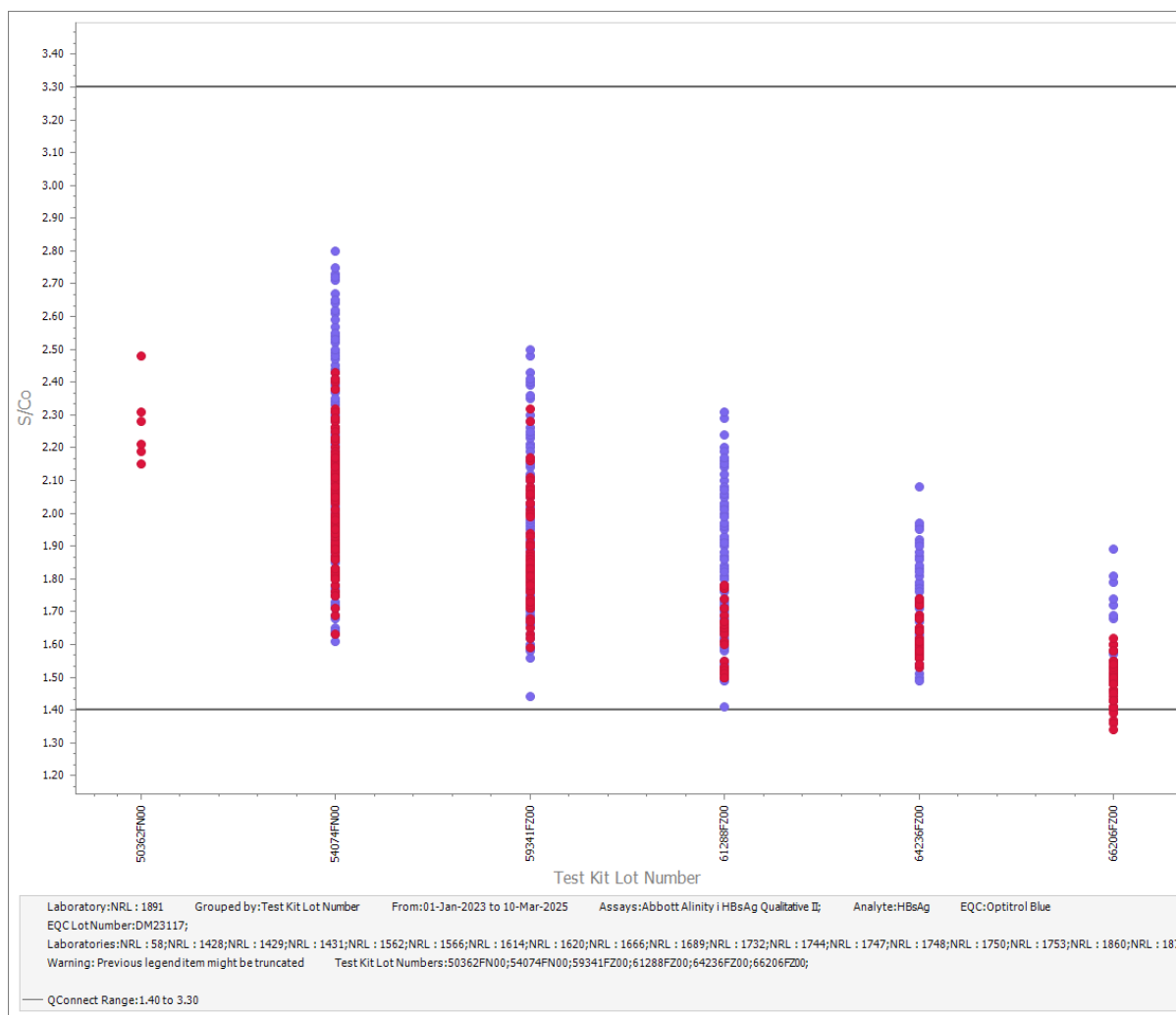
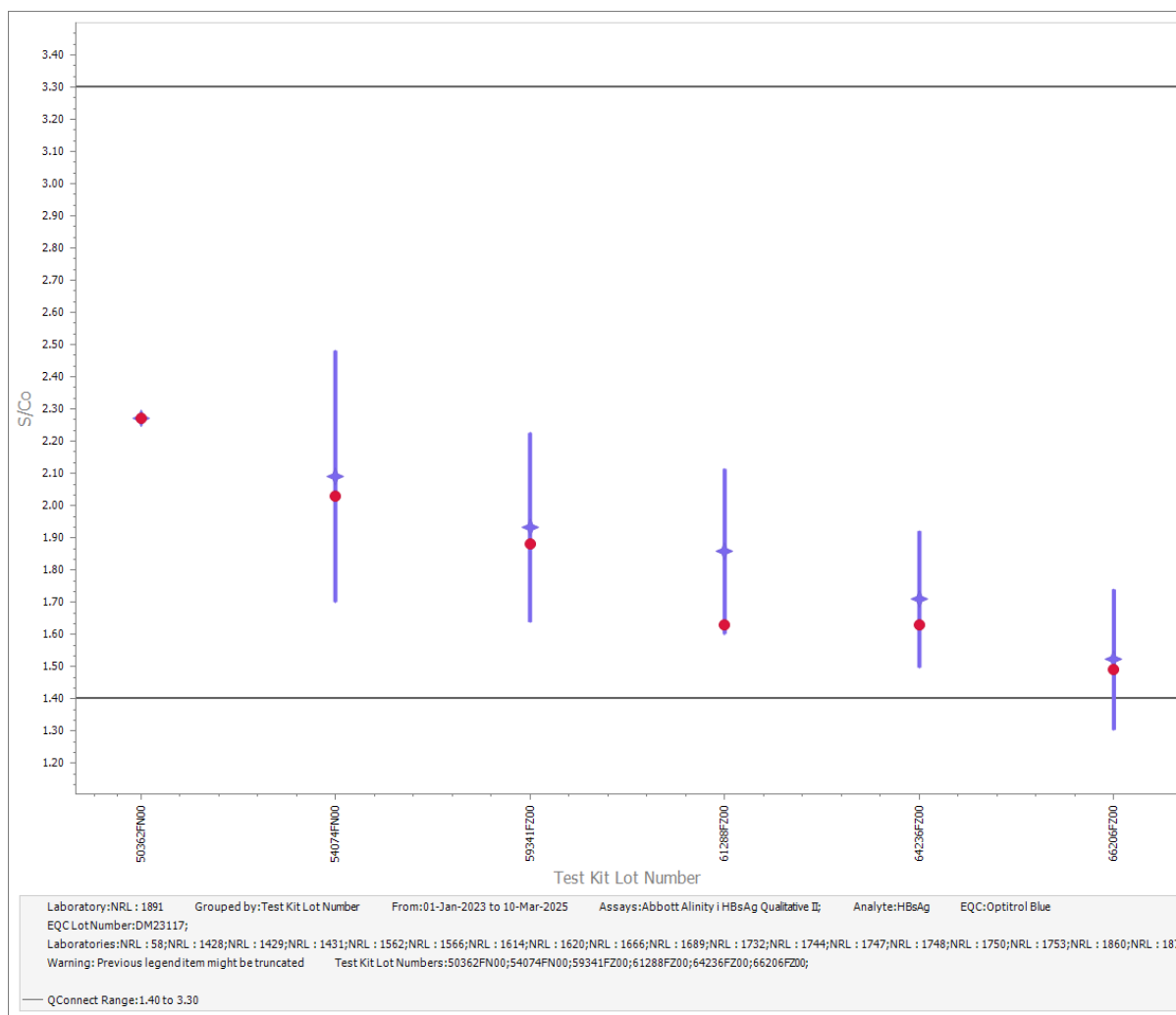
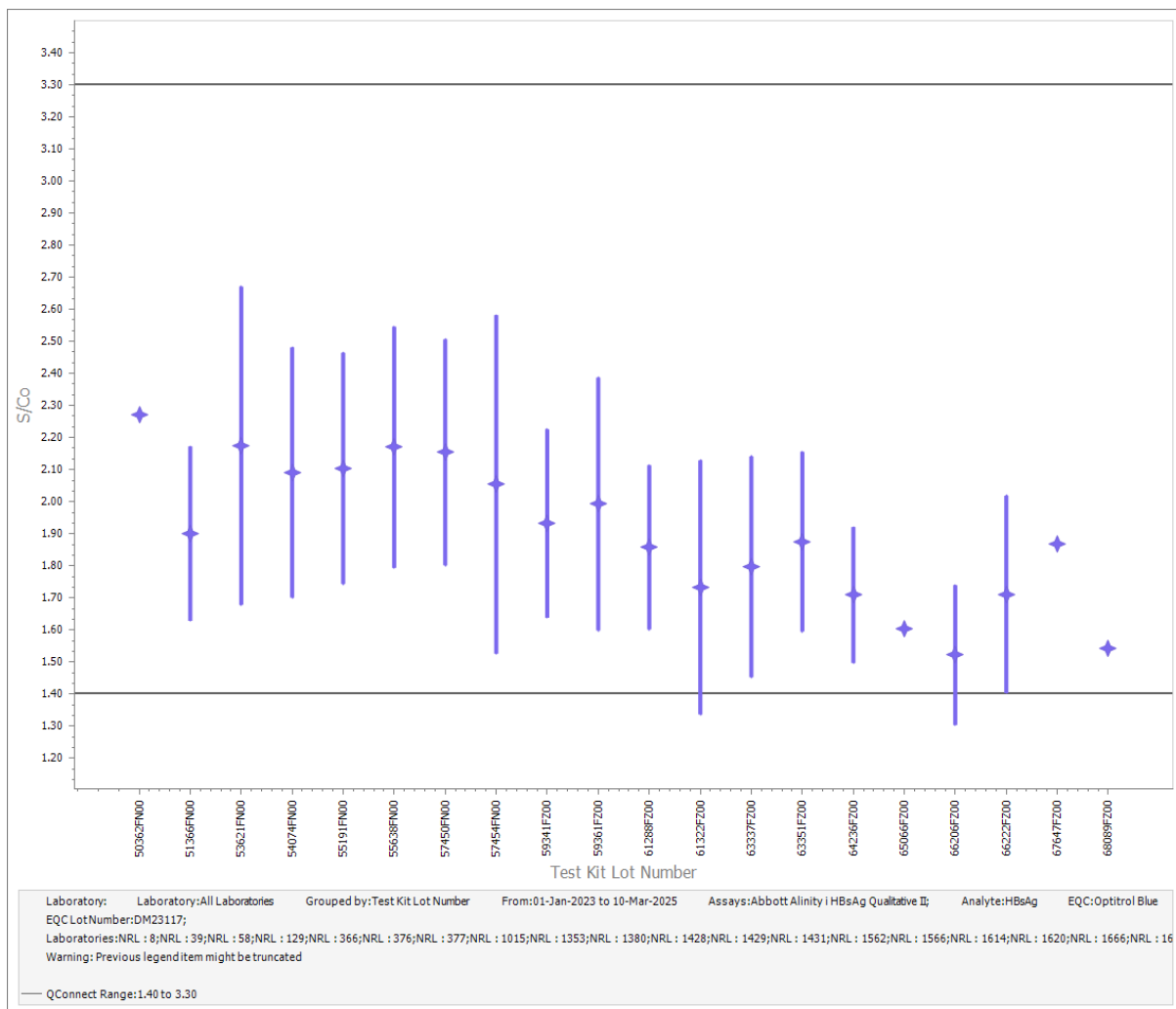


Figure 5- Peer group data reported on the Abbott Alinity i HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 1891.





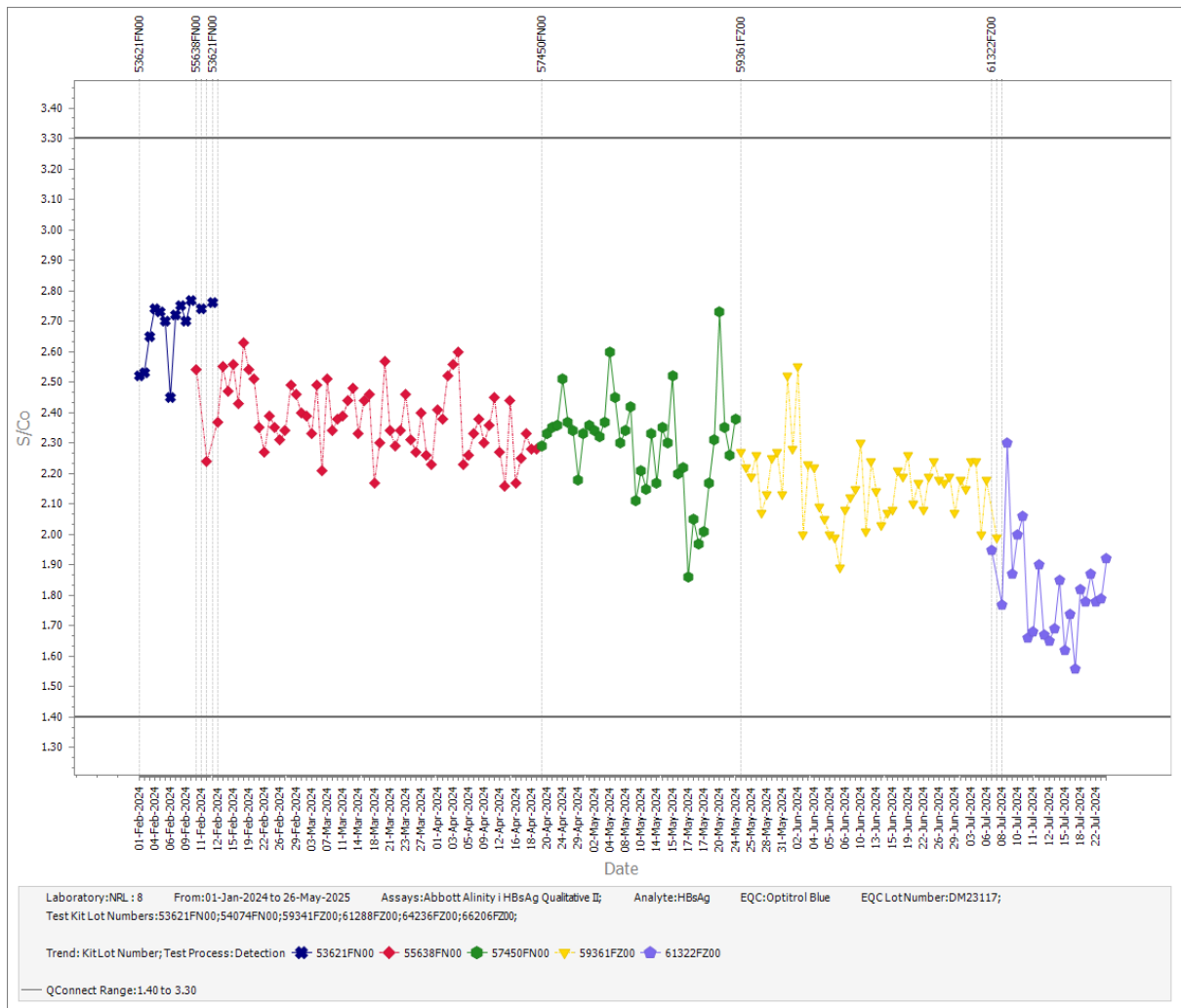


Figure 8- Participant 8 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

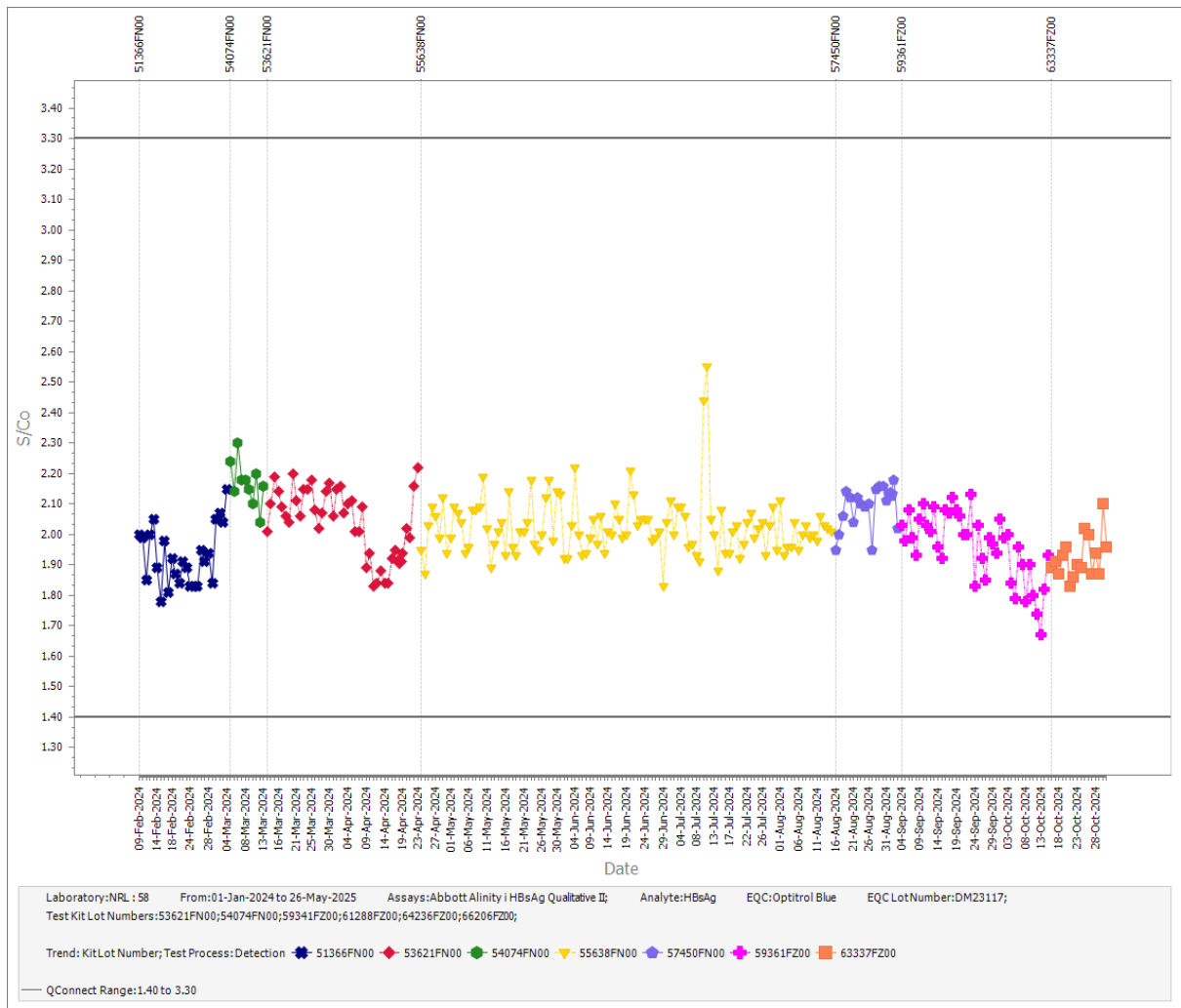


Figure 9- Participant 58 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

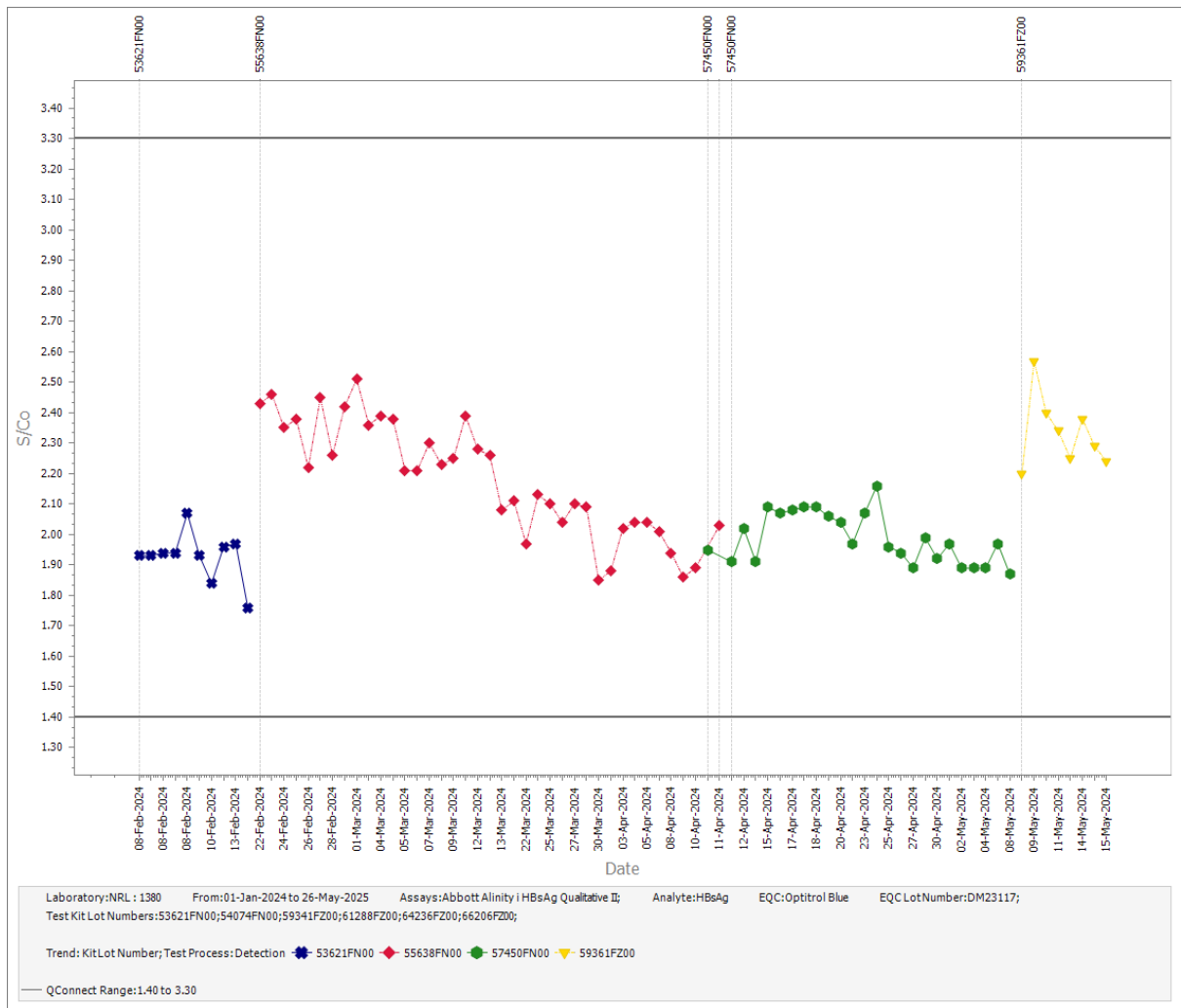


Figure 10- Participant 1380 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

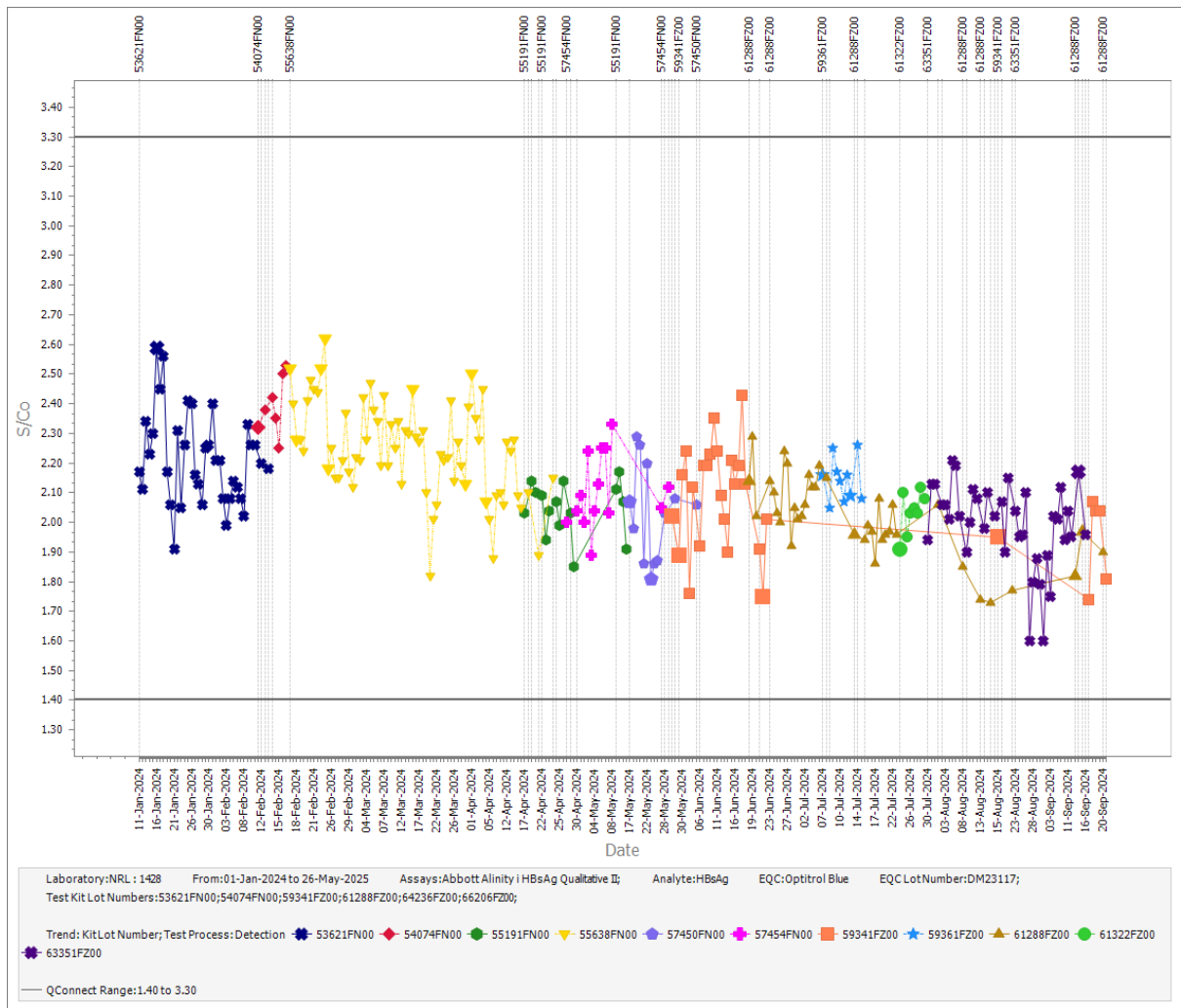


Figure 11- Participant 1428 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

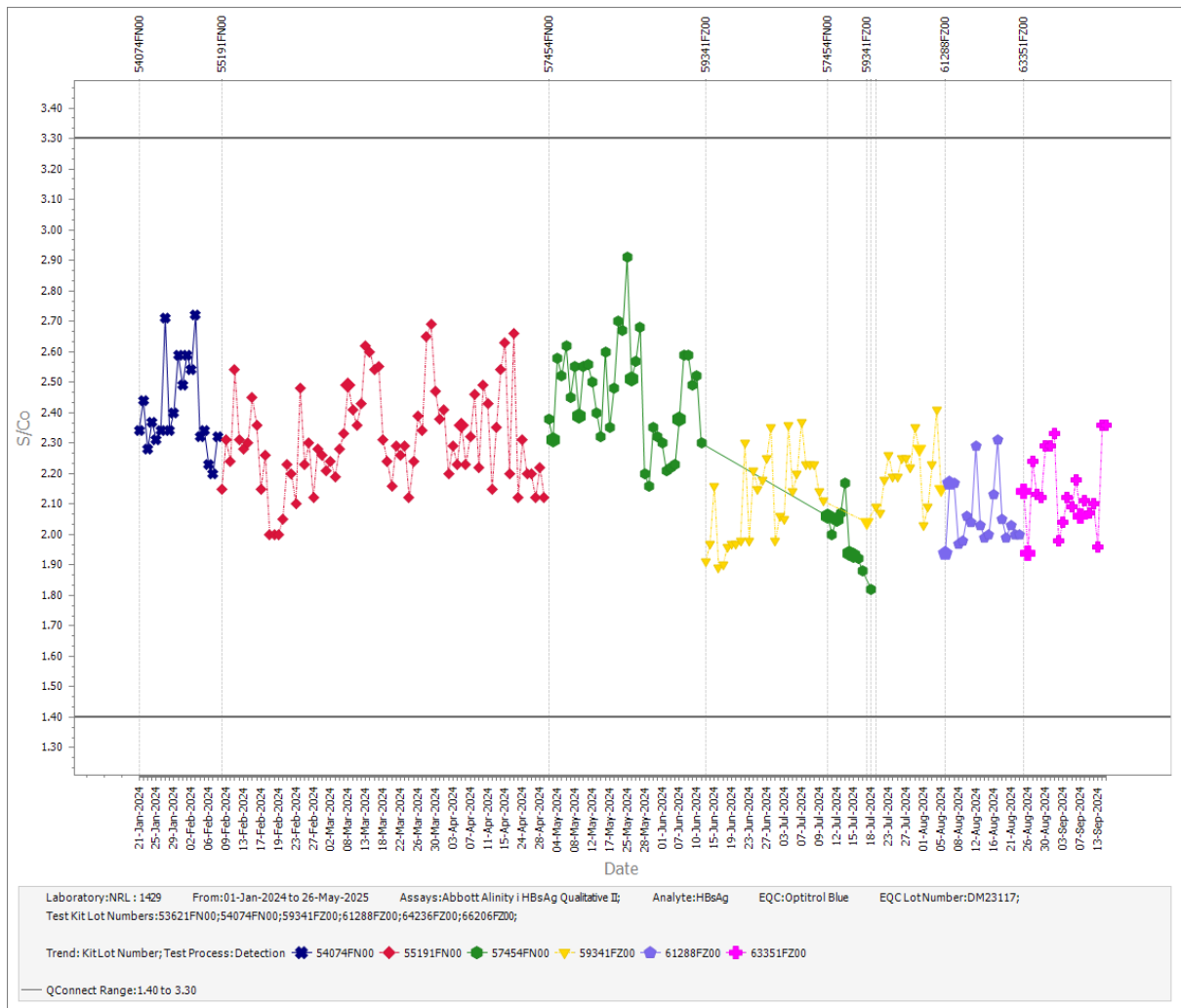


Figure 12- Participant 1429 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

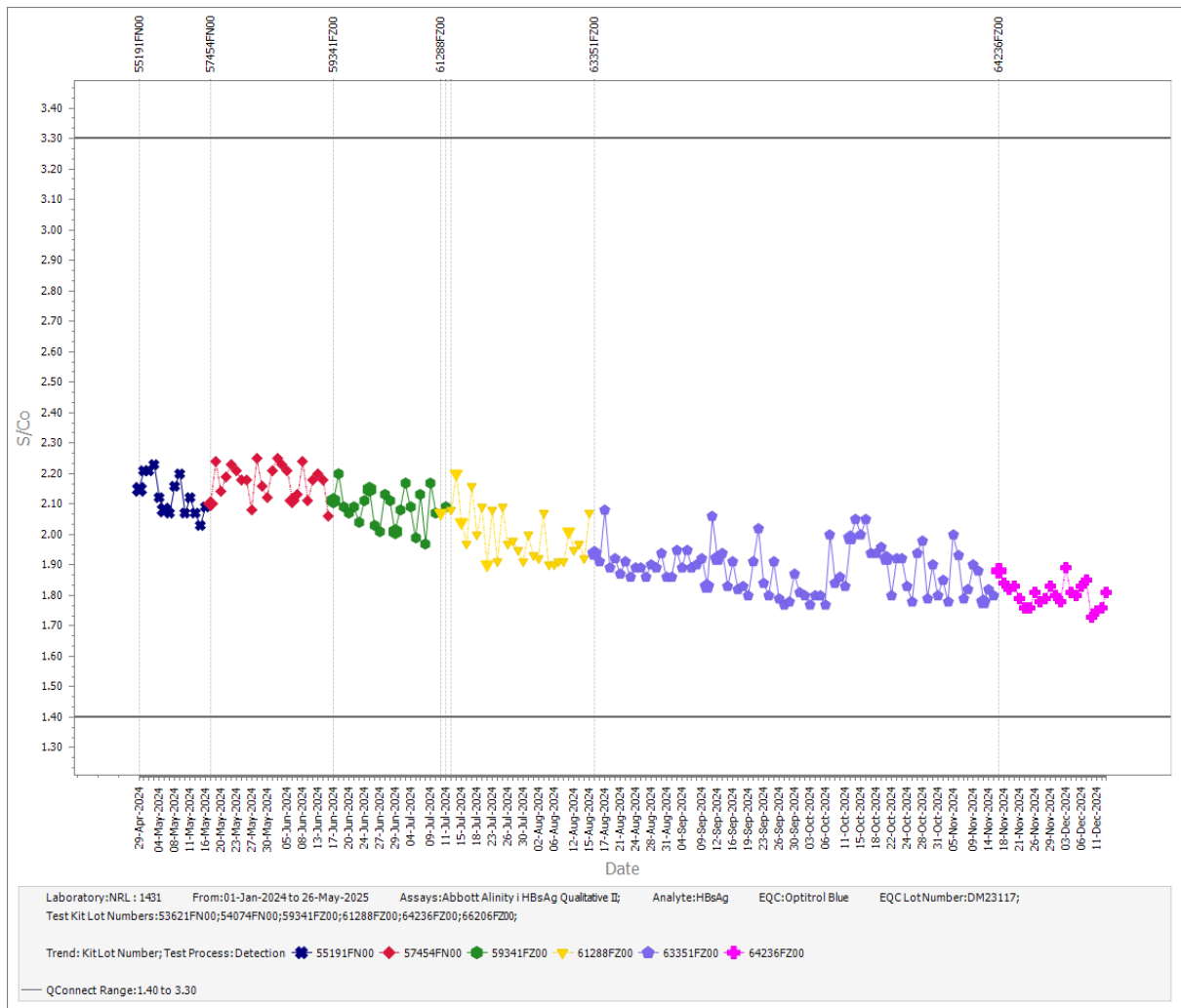


Figure 13- Participant 1431 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

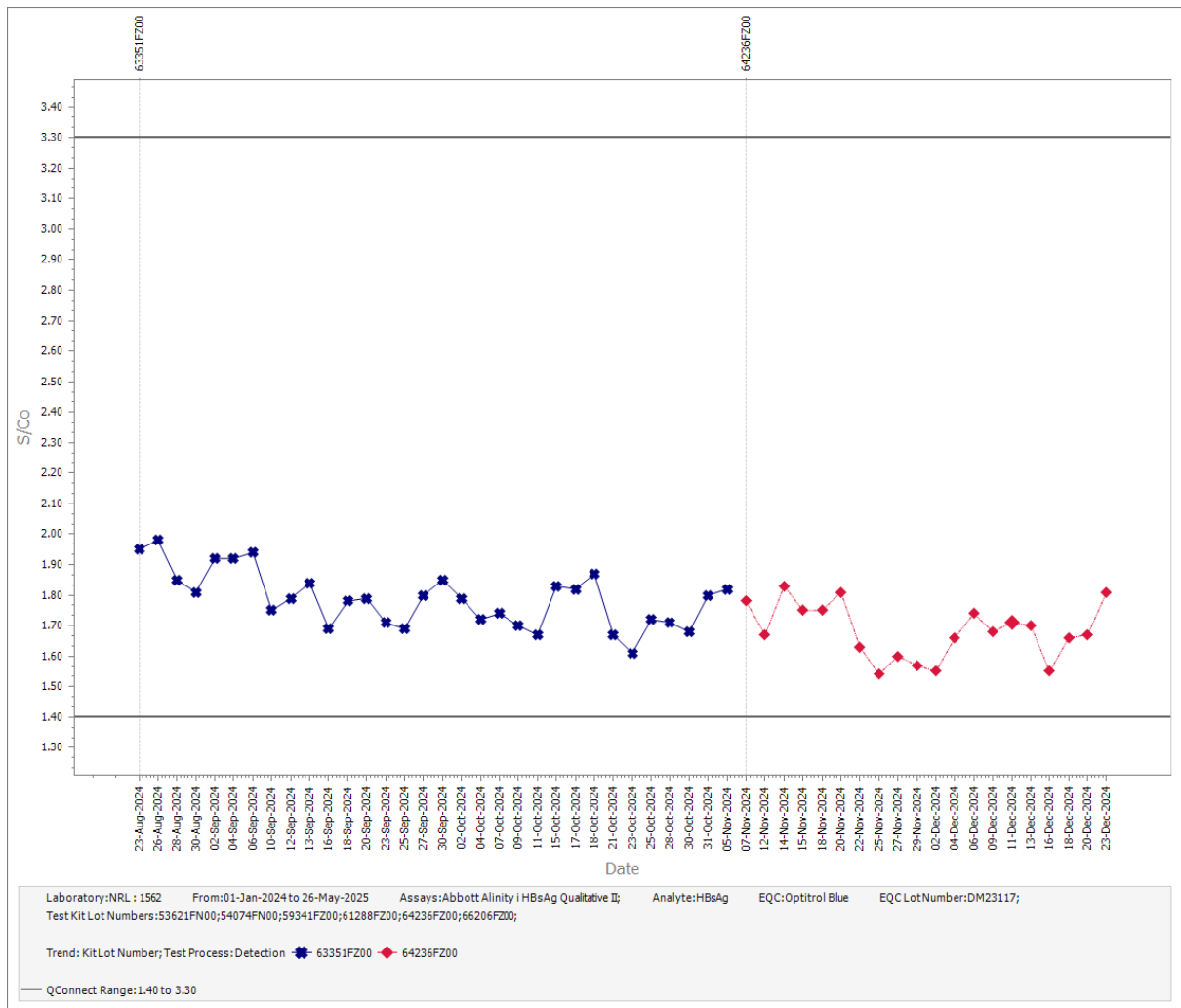


Figure 14- Participant 1562 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

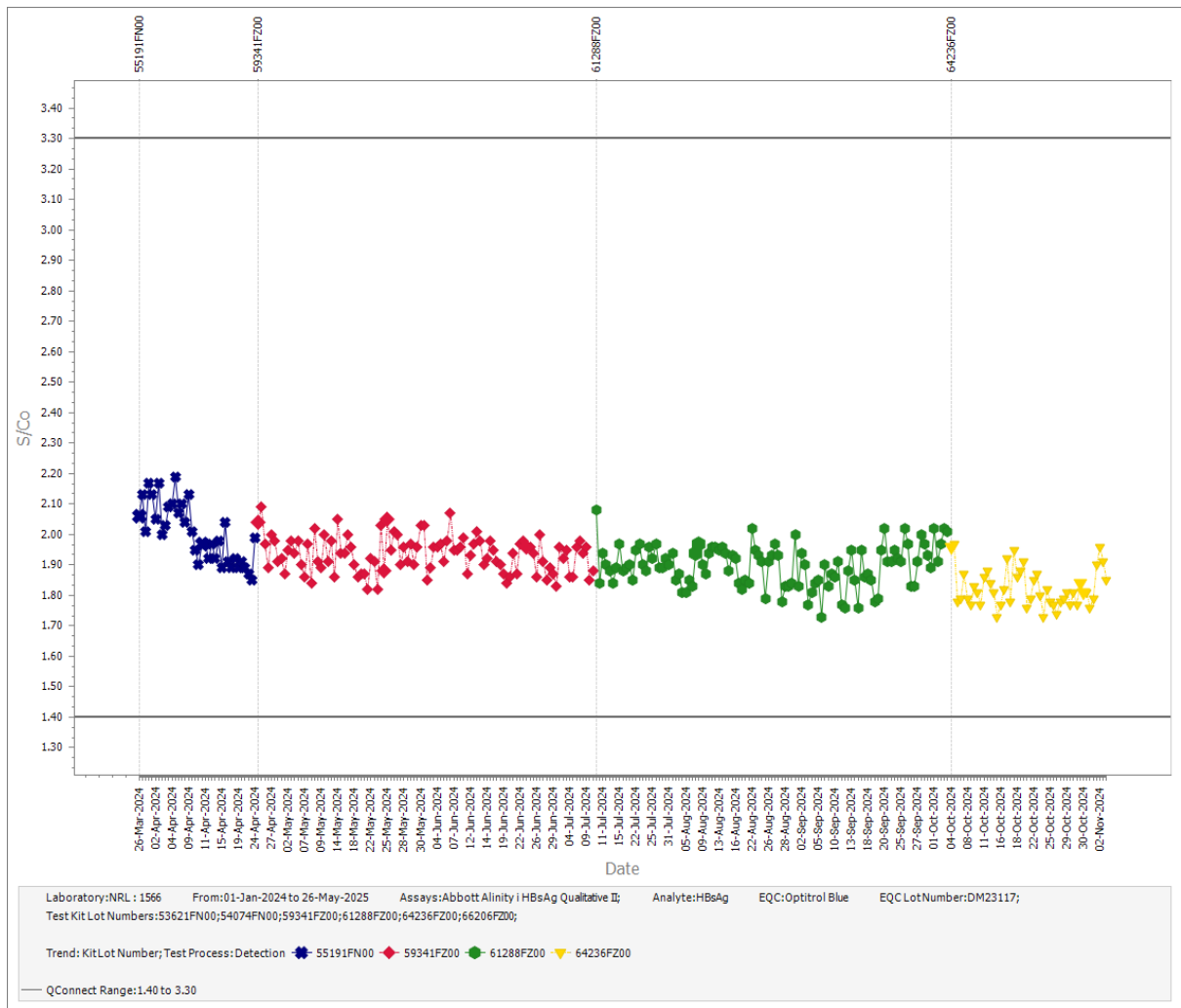


Figure 15- Participant 1566 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

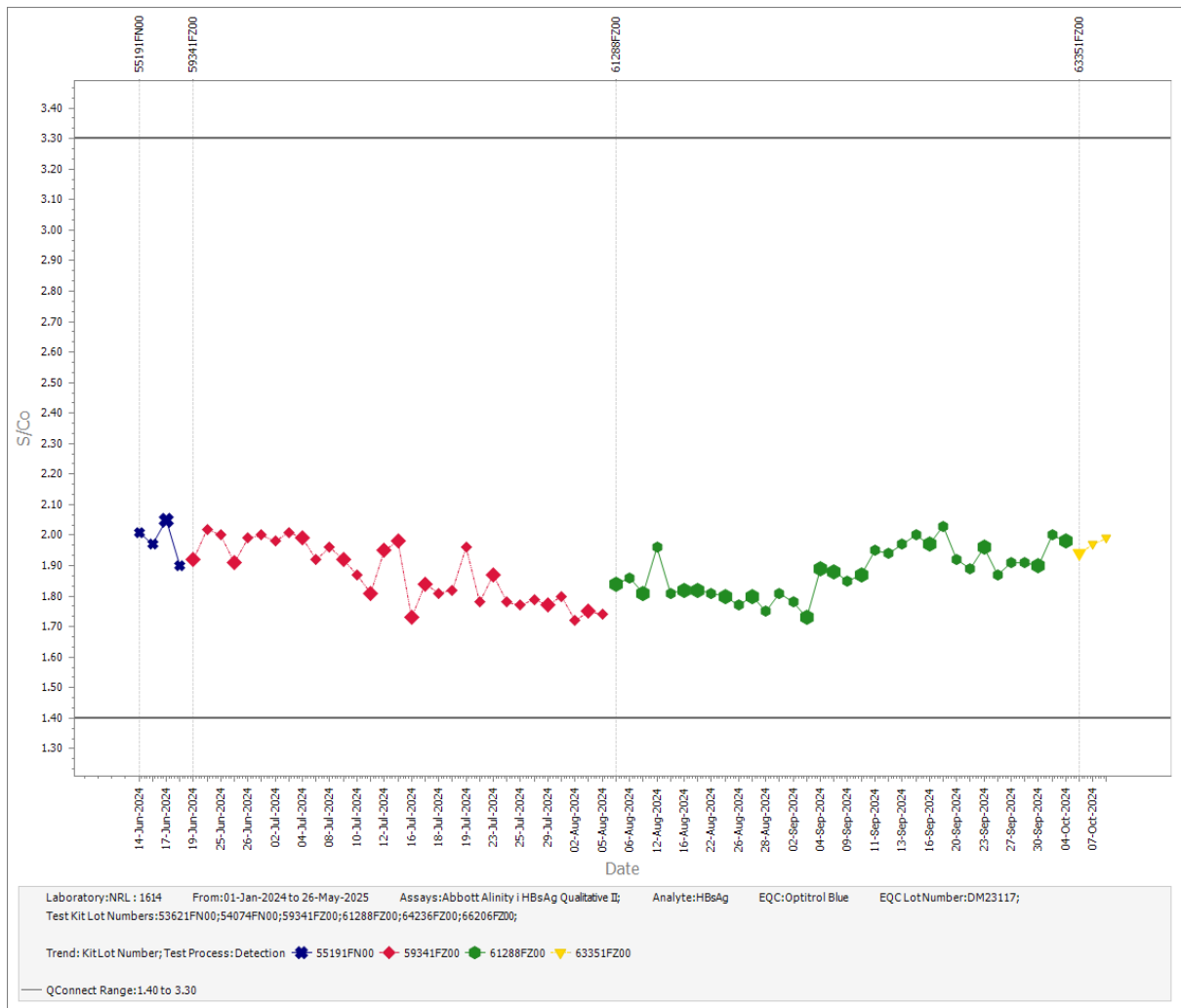


Figure 16- Participant 1614 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

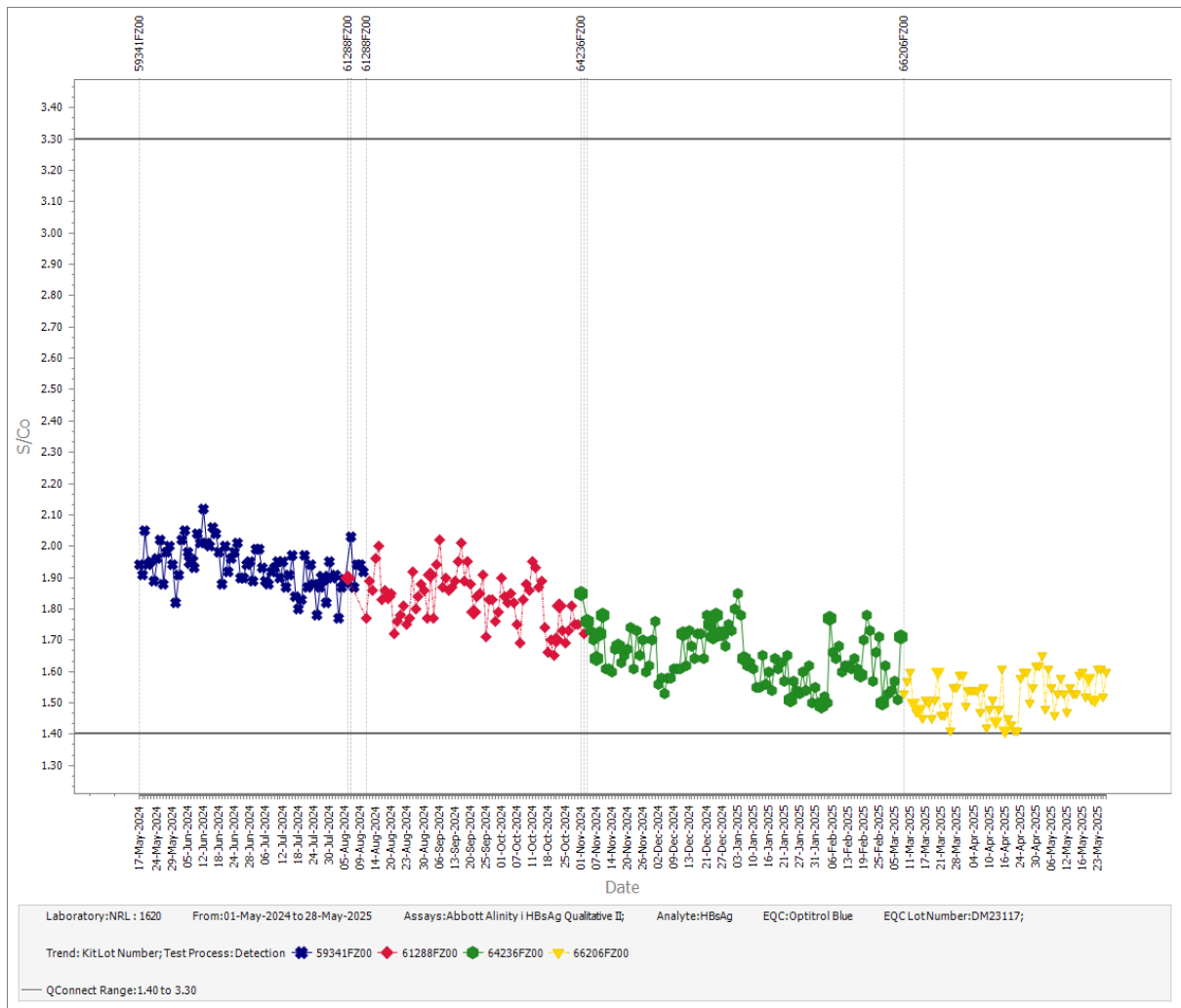


Figure 17- Participant 1620 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

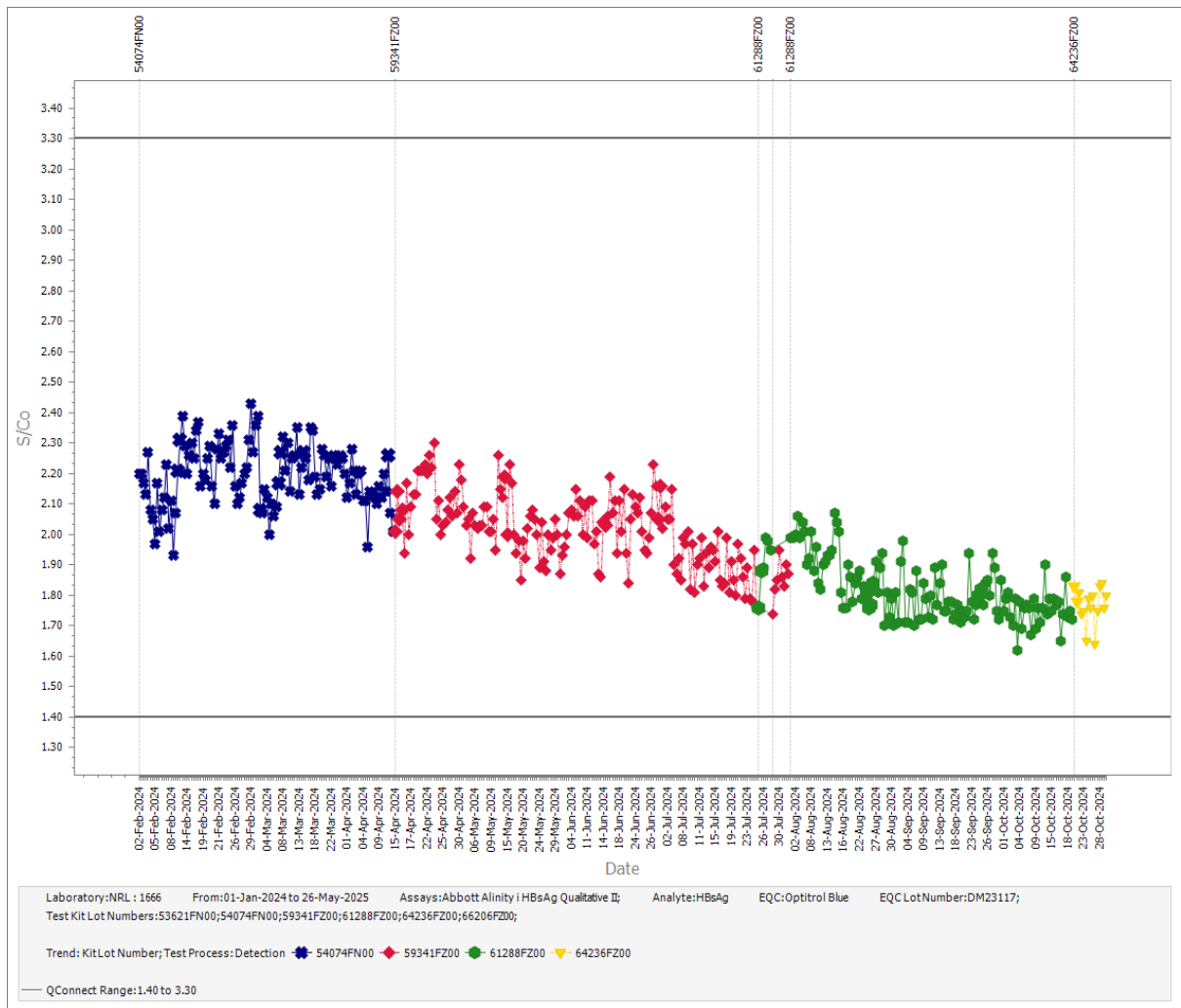


Figure 18- Participant 1666 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

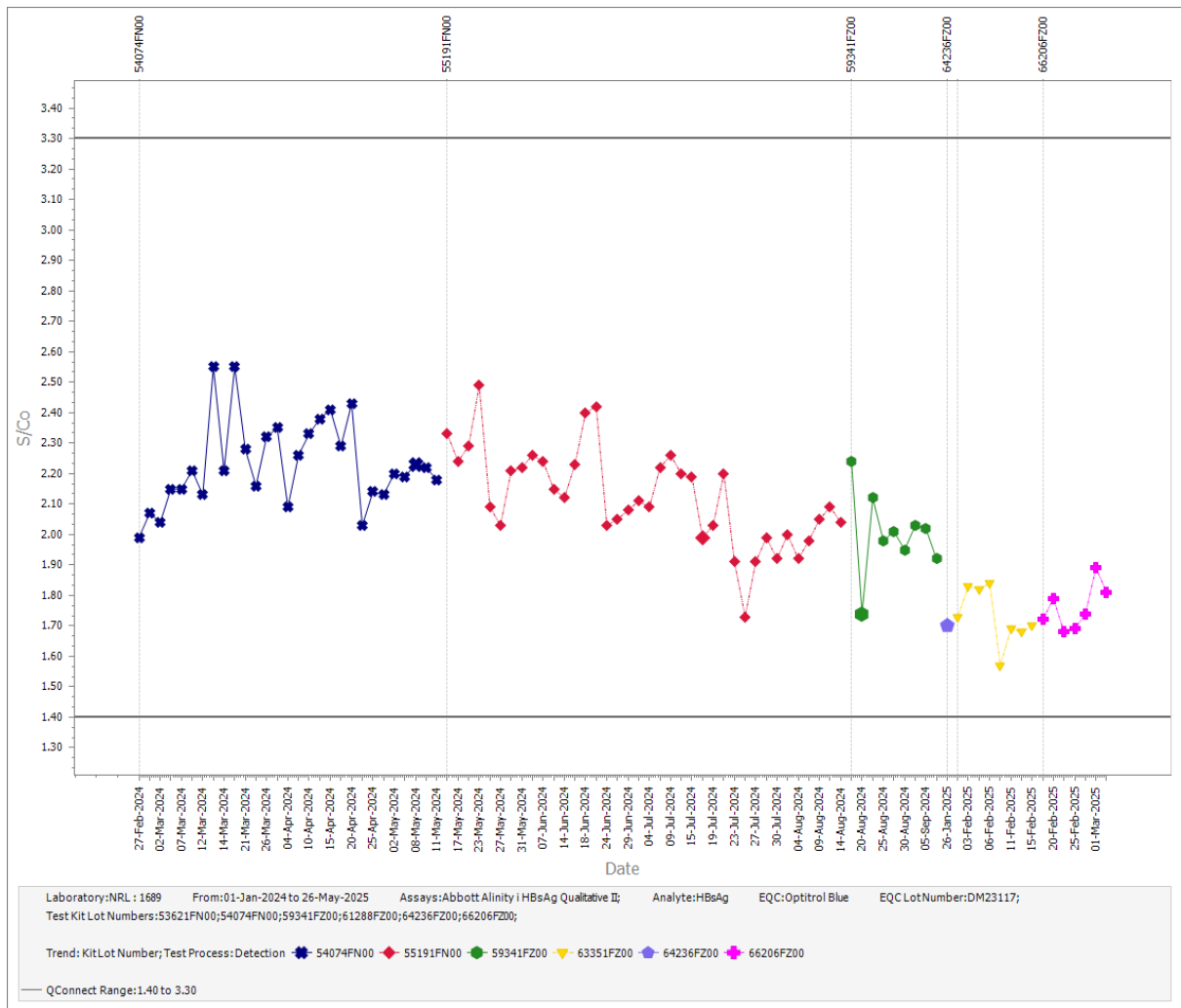


Figure 19- Participant 1689 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

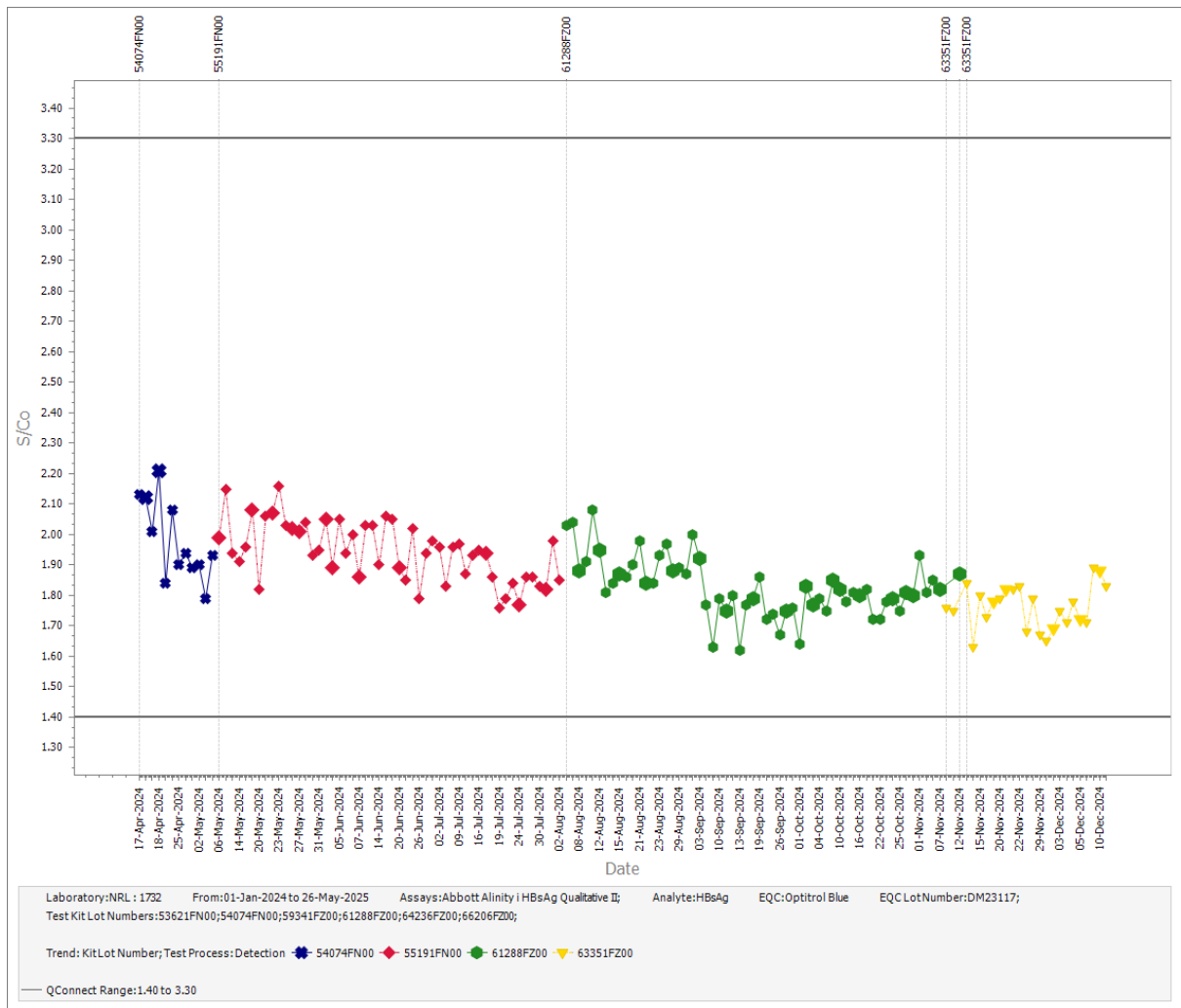


Figure 20- Participant 1732 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

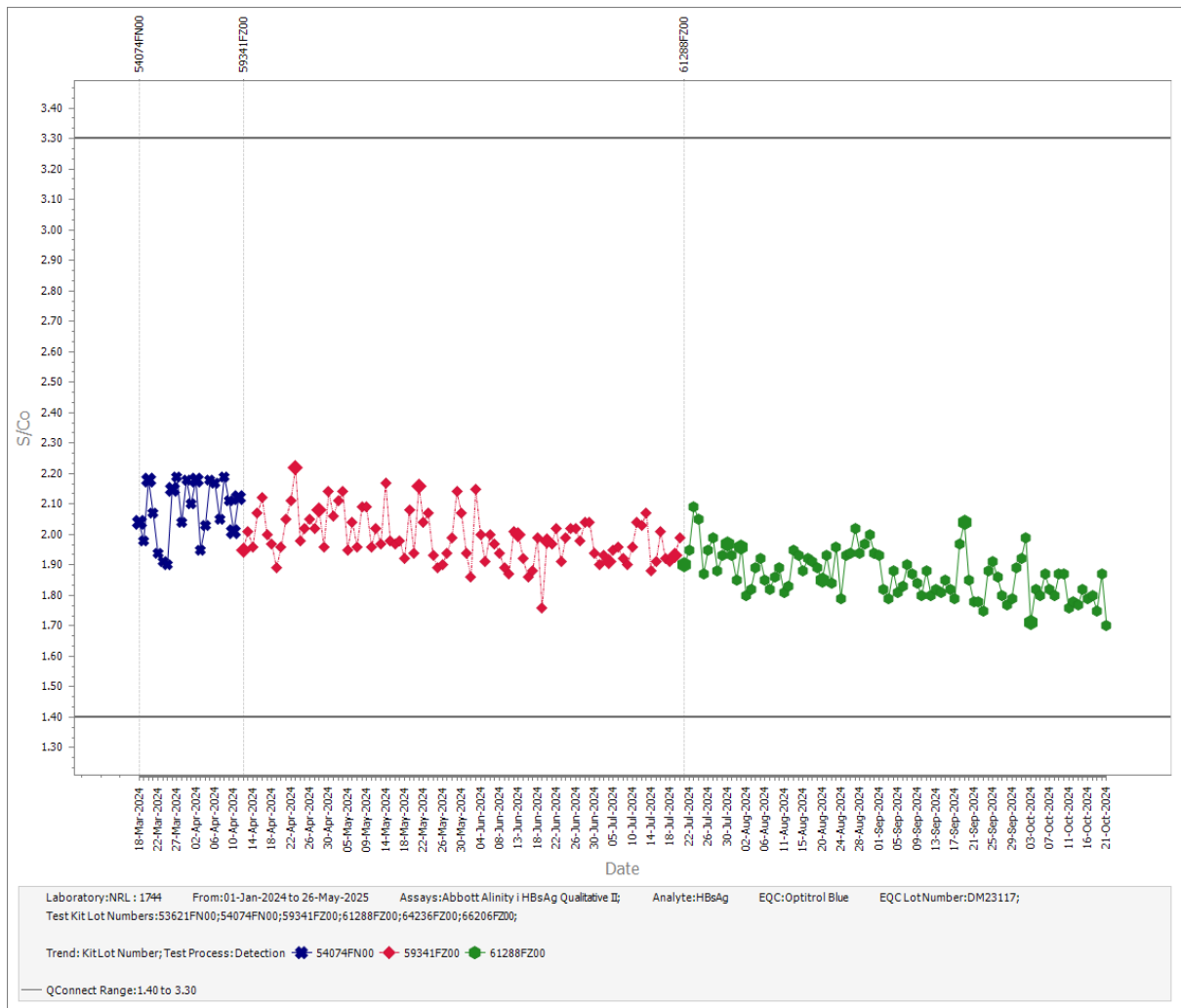


Figure 21- Participant 1744 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

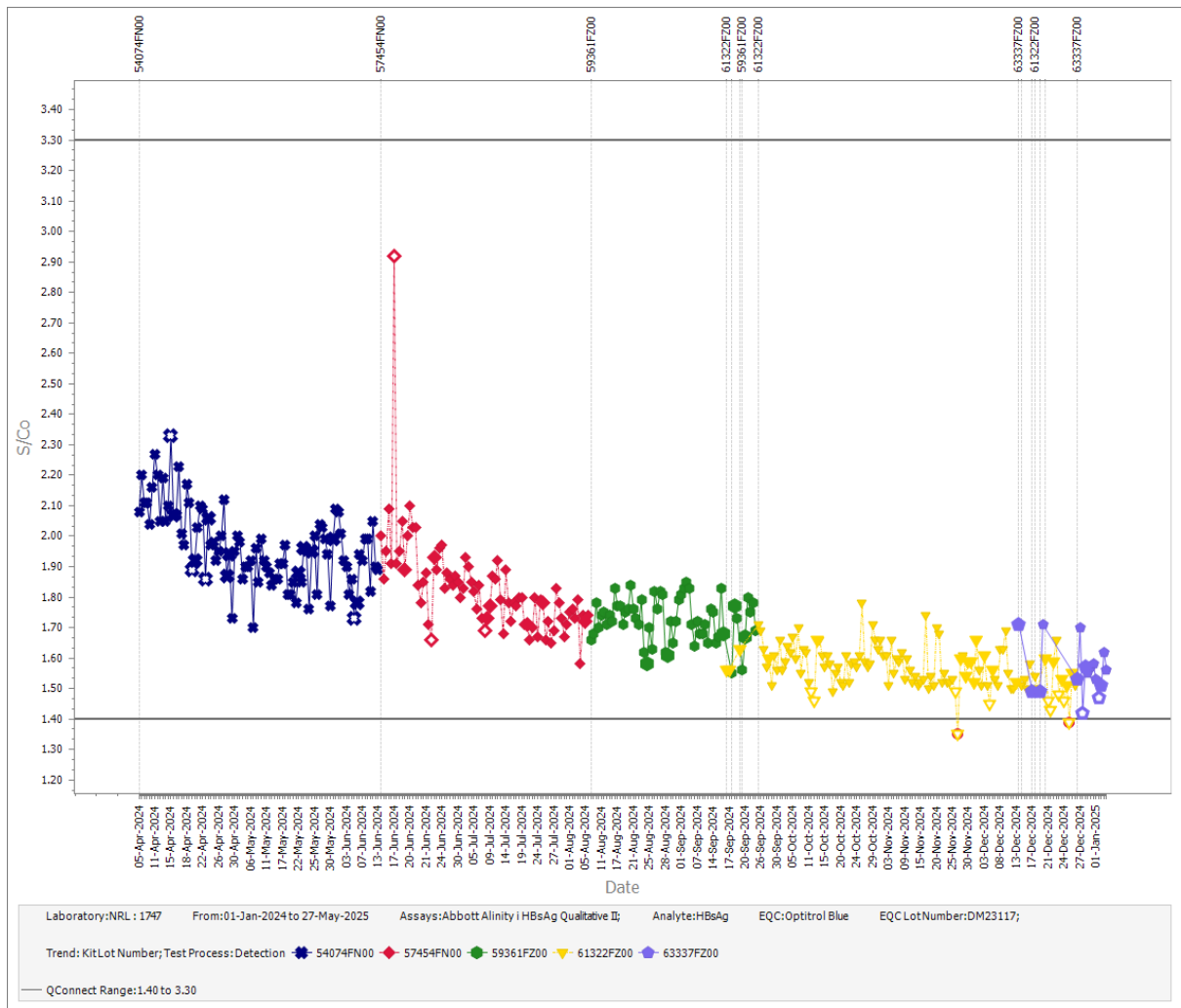


Figure 22- Participant 1747 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

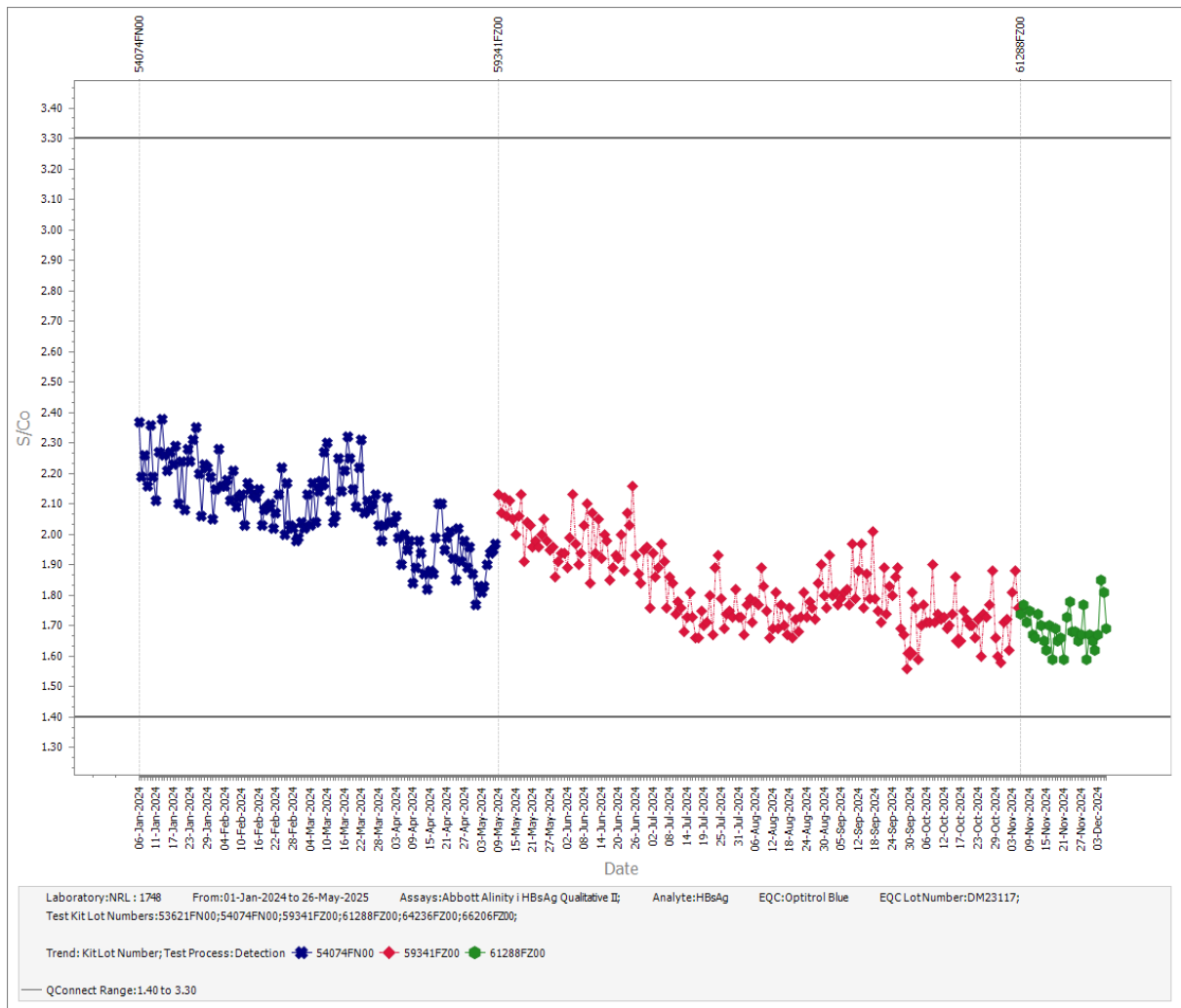


Figure 23- Participant 1748 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

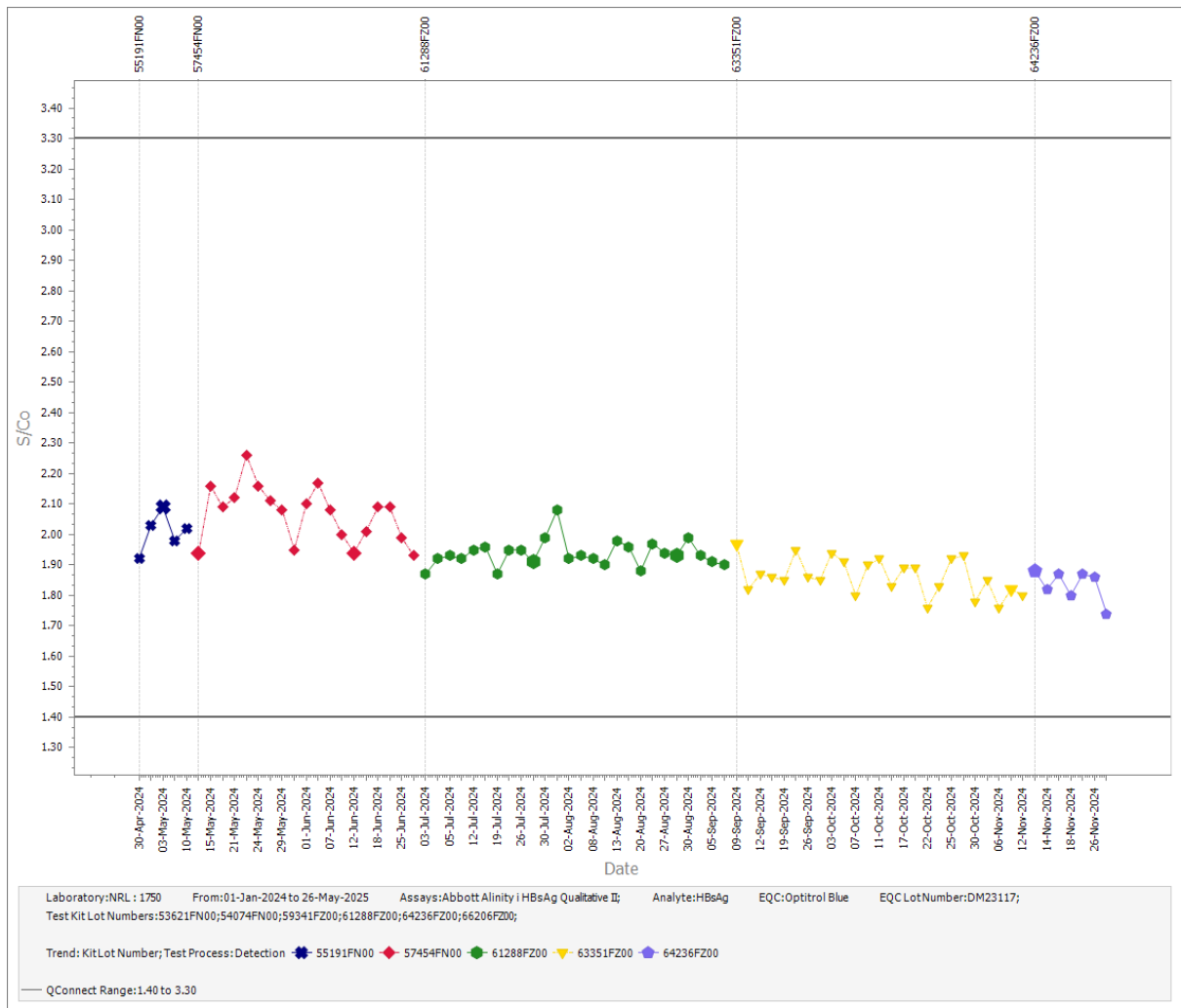


Figure 24 Participant 1750 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

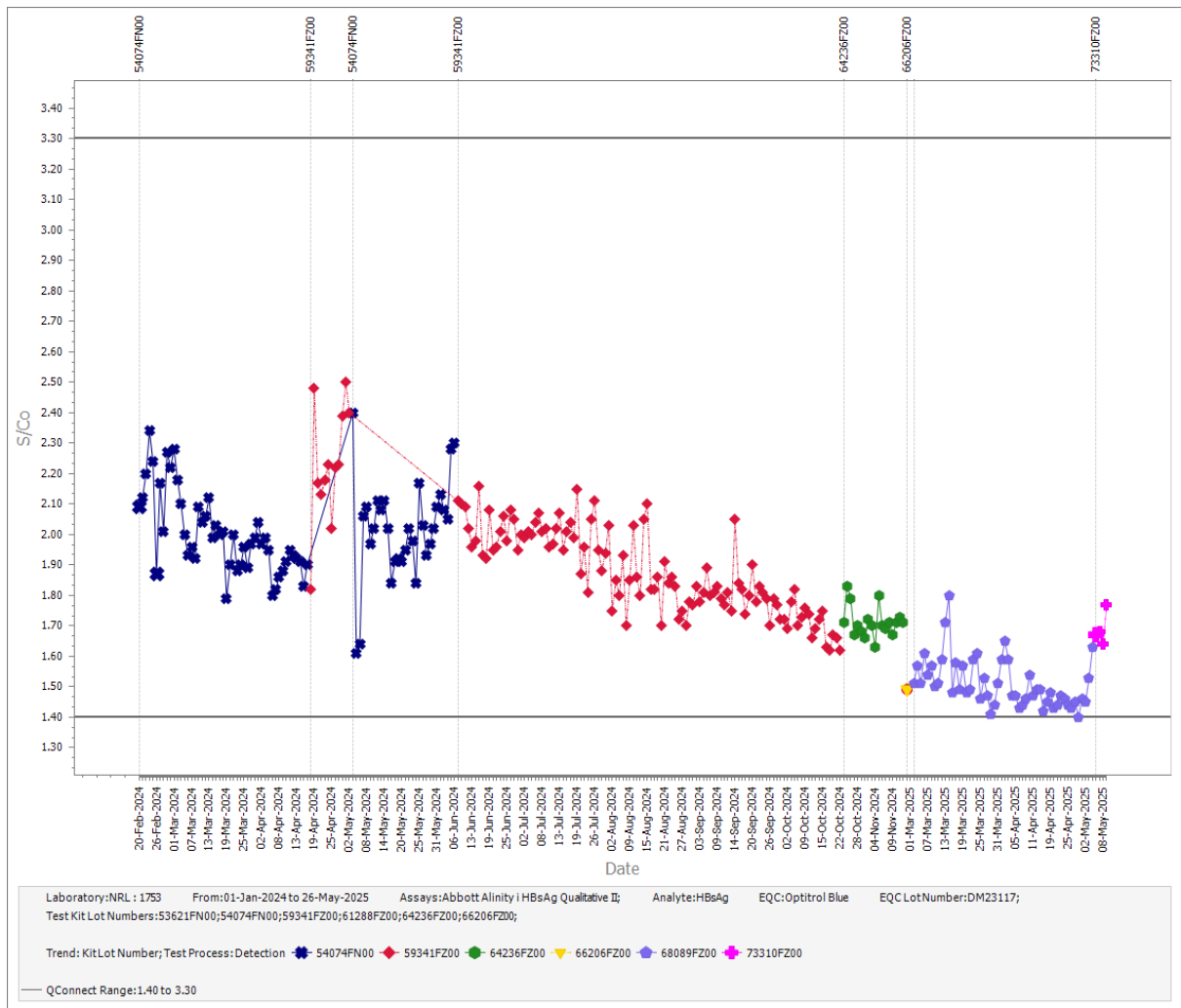


Figure 25- Participant 1753 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

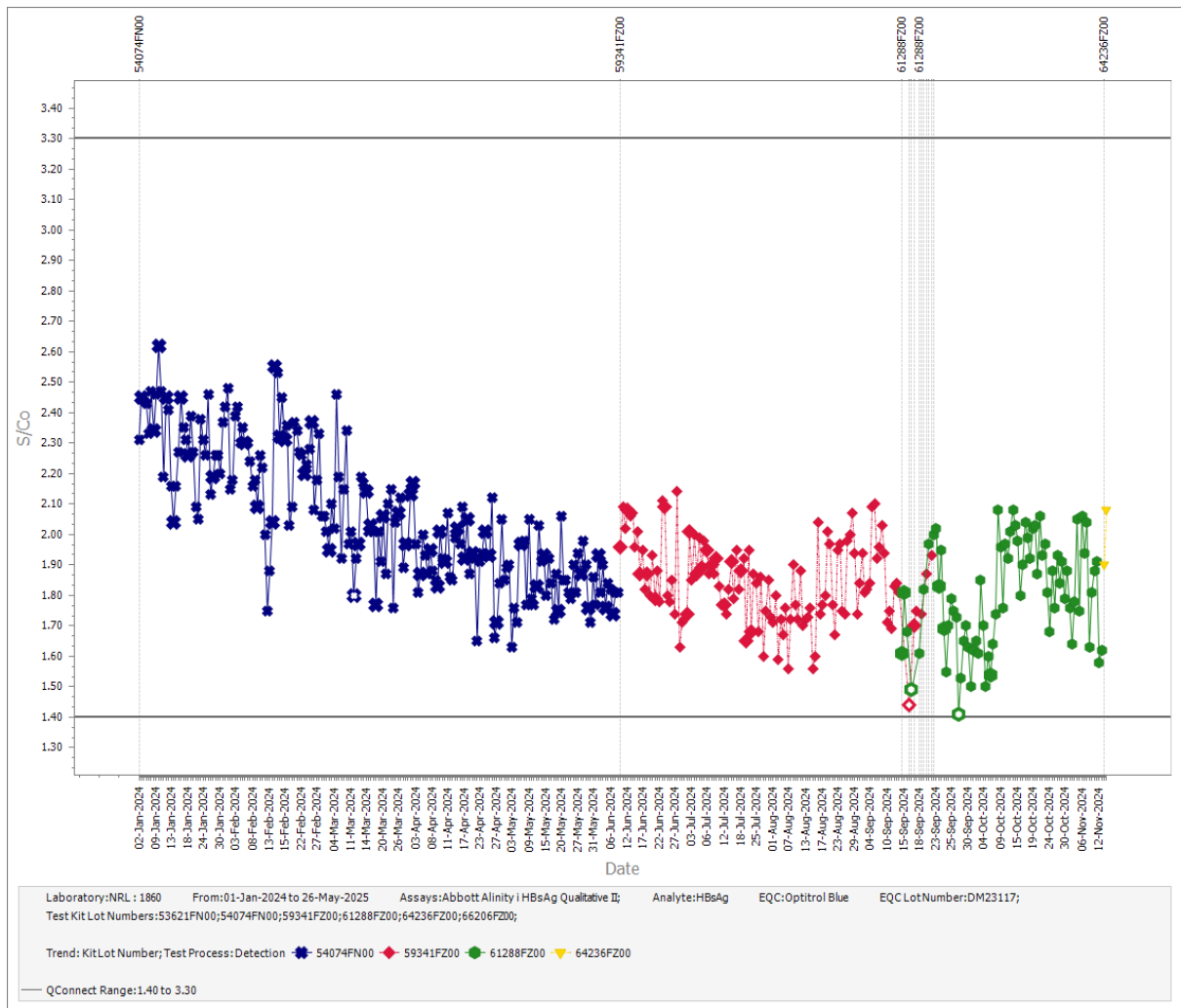


Figure 26- Participant 1860 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

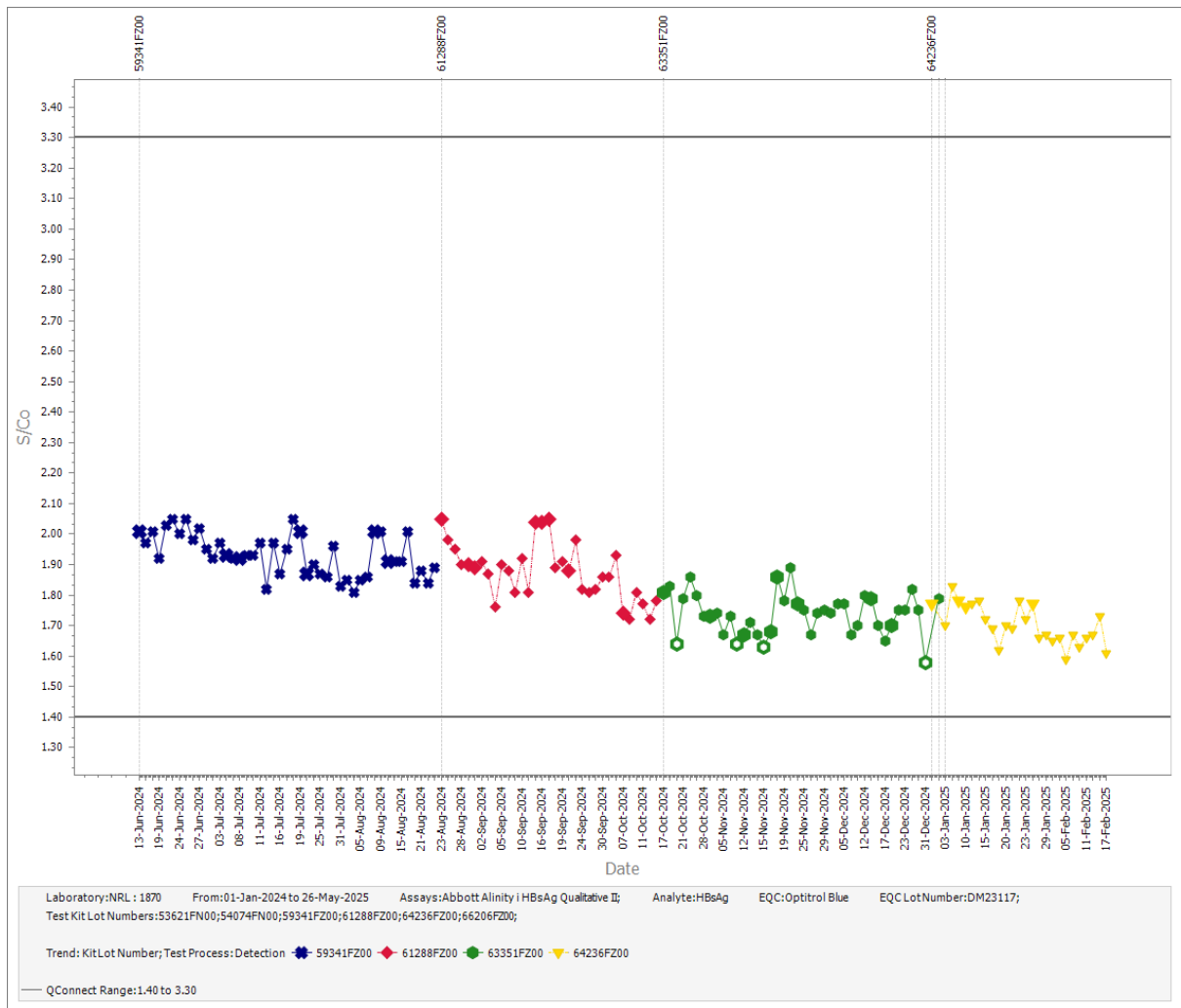


Figure 27- Participant 1870 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

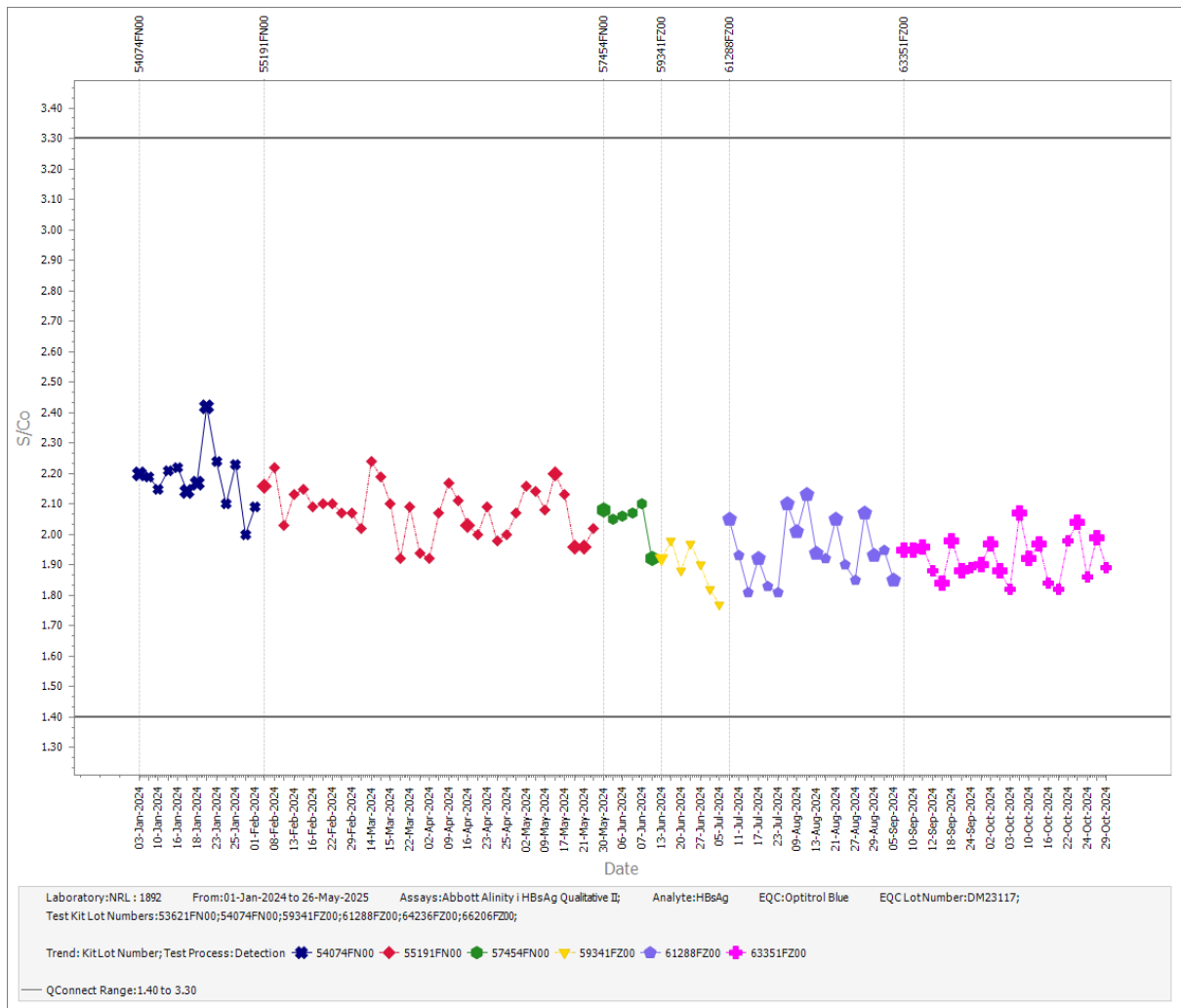


Figure 28- Participant 1892 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

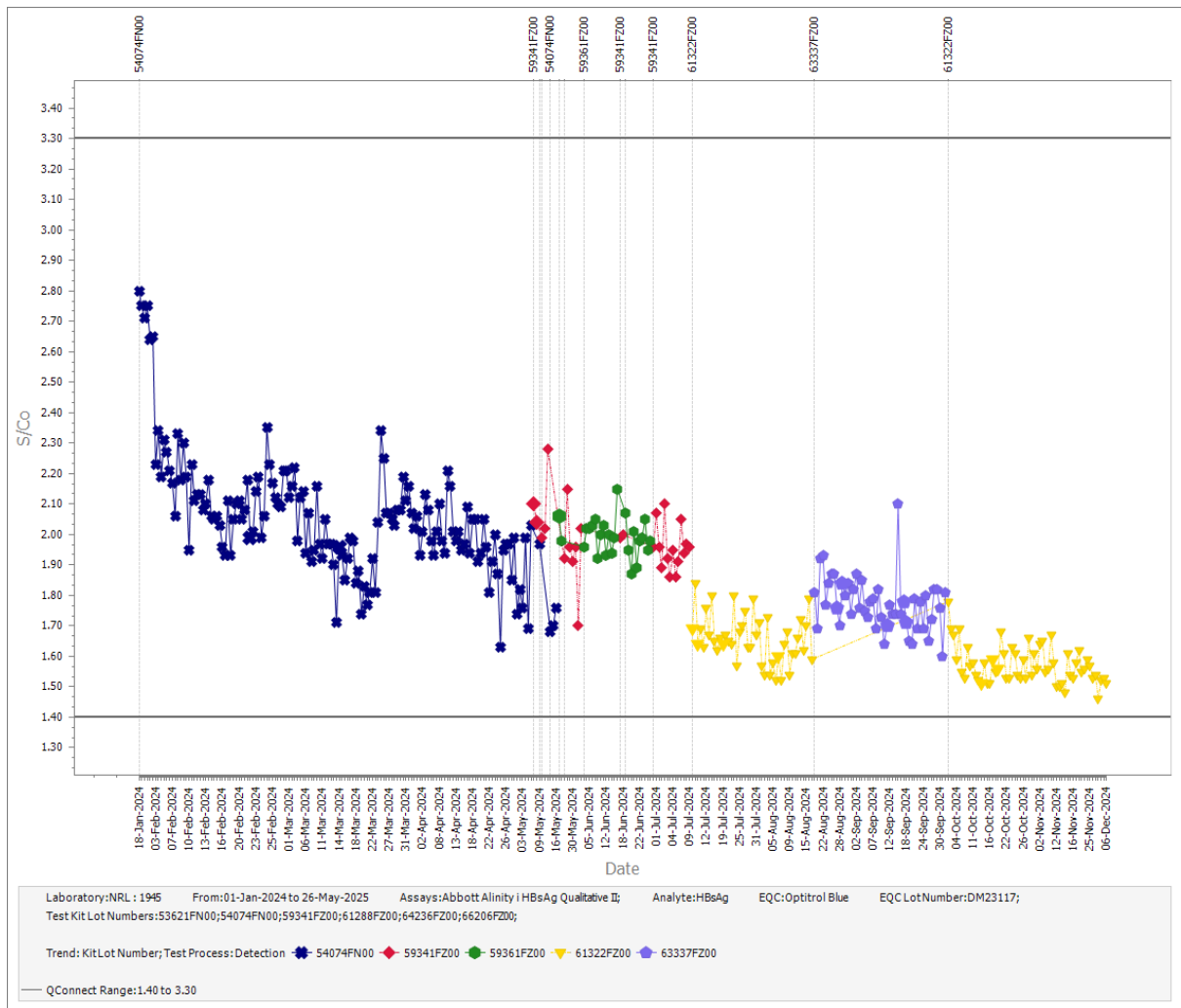


Figure 29- Participant 1945 data reported on the Abbott Alinity i HBsAg Qualitative II for Optitrol Blue DM23117.

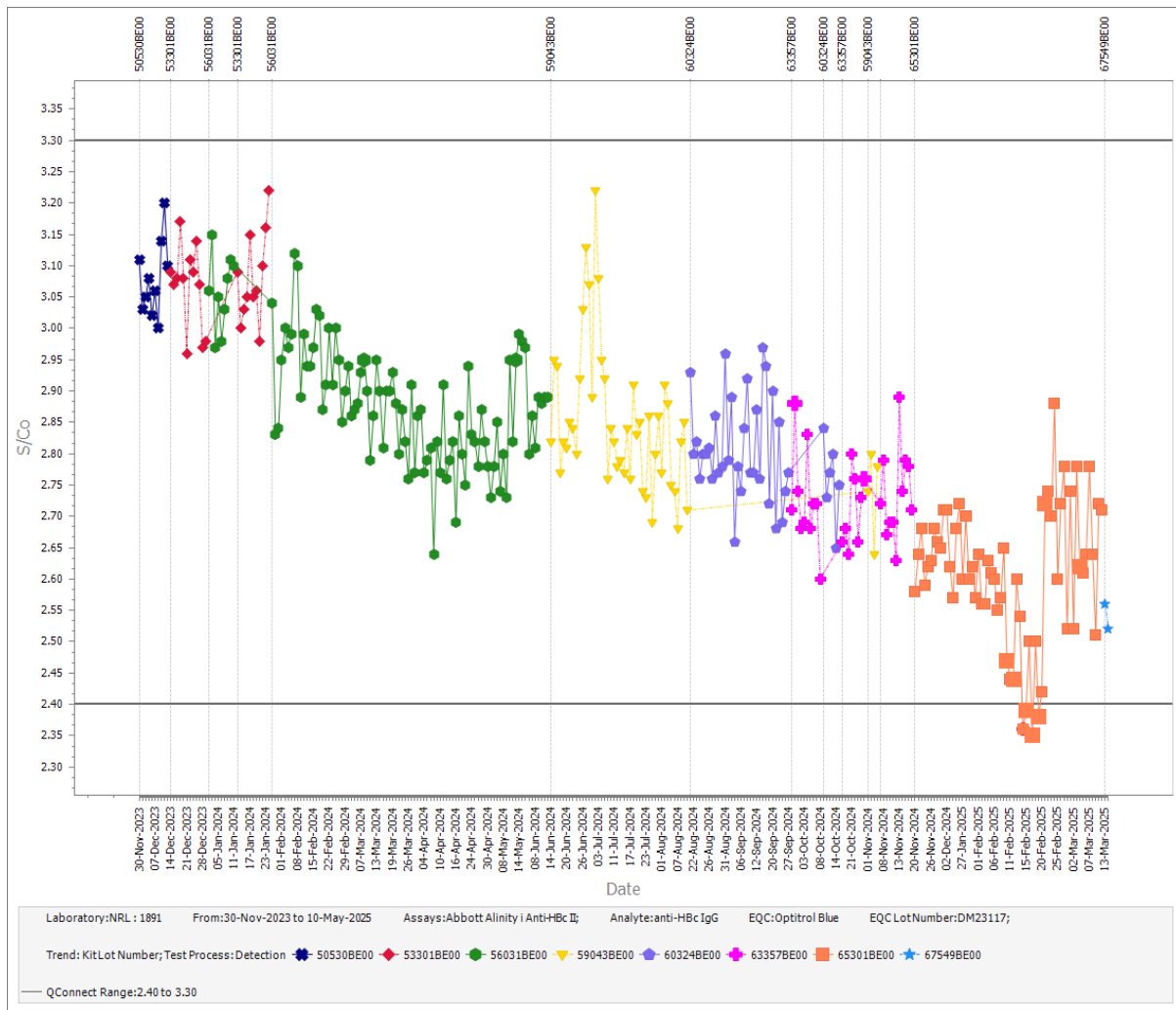


Figure 30- Participant 1891 data reported on the Abbott Alinity i Anti-HBc II assay for Optitrol Blue DM23117.

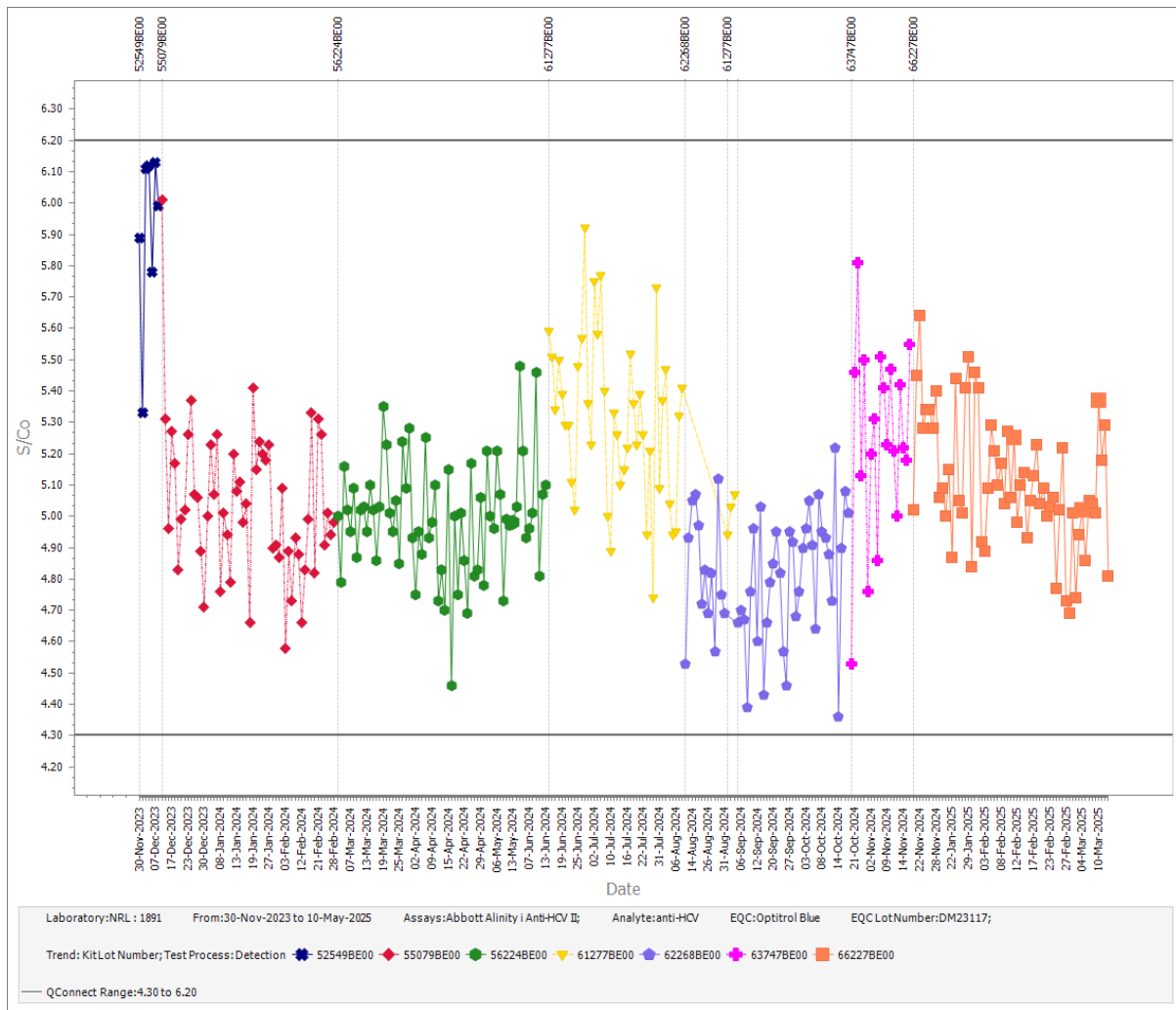


Figure 31- Participant 1891 data reported on the Abbott Alinity i Anti-HCV II assay for Optitrol Blue DM23117.

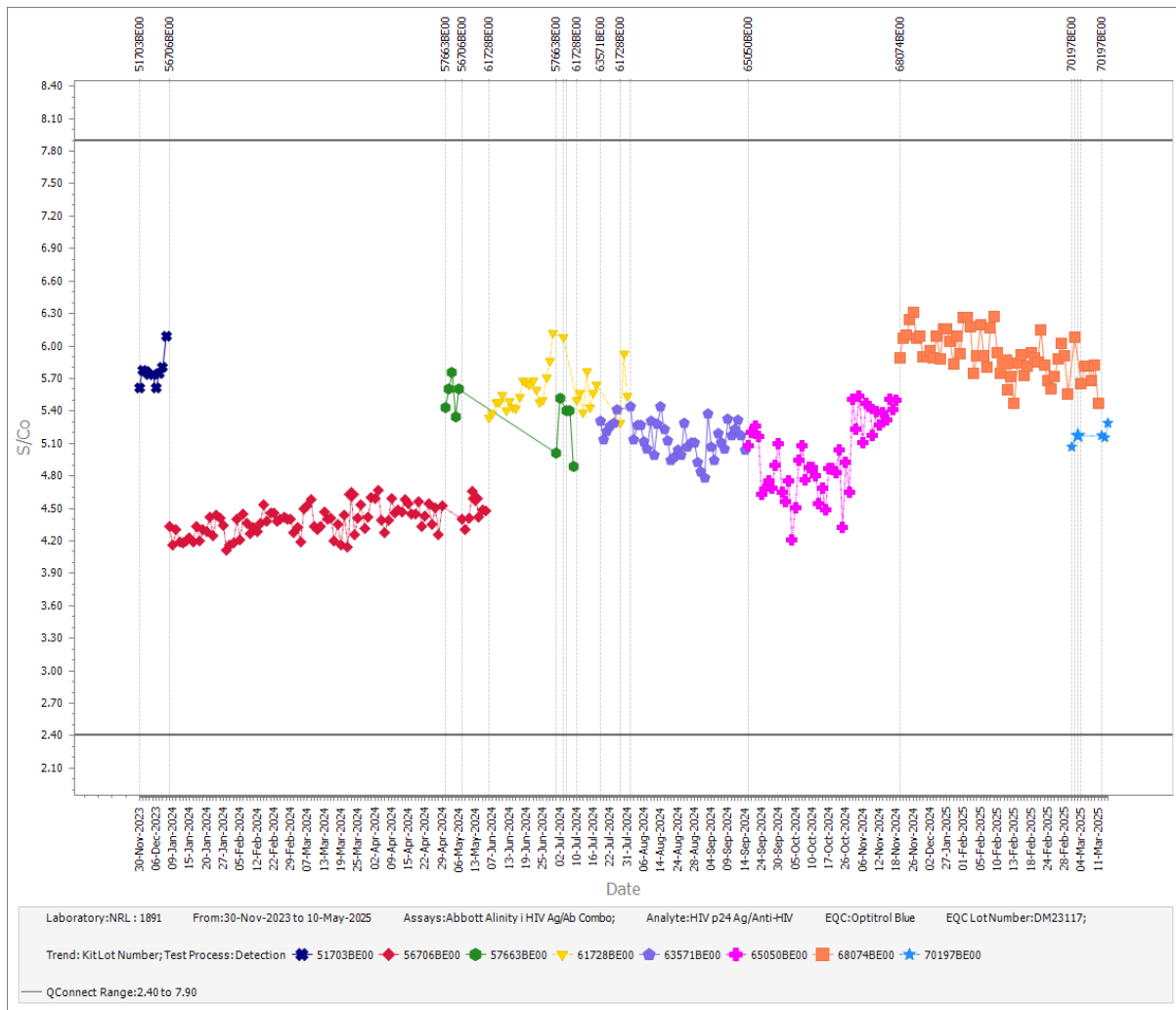


Figure 32- Participant 1891 data reported on the Abbott Alinity i HIV Ag/Ab Combo assay for Optitrol Blue DM23117.

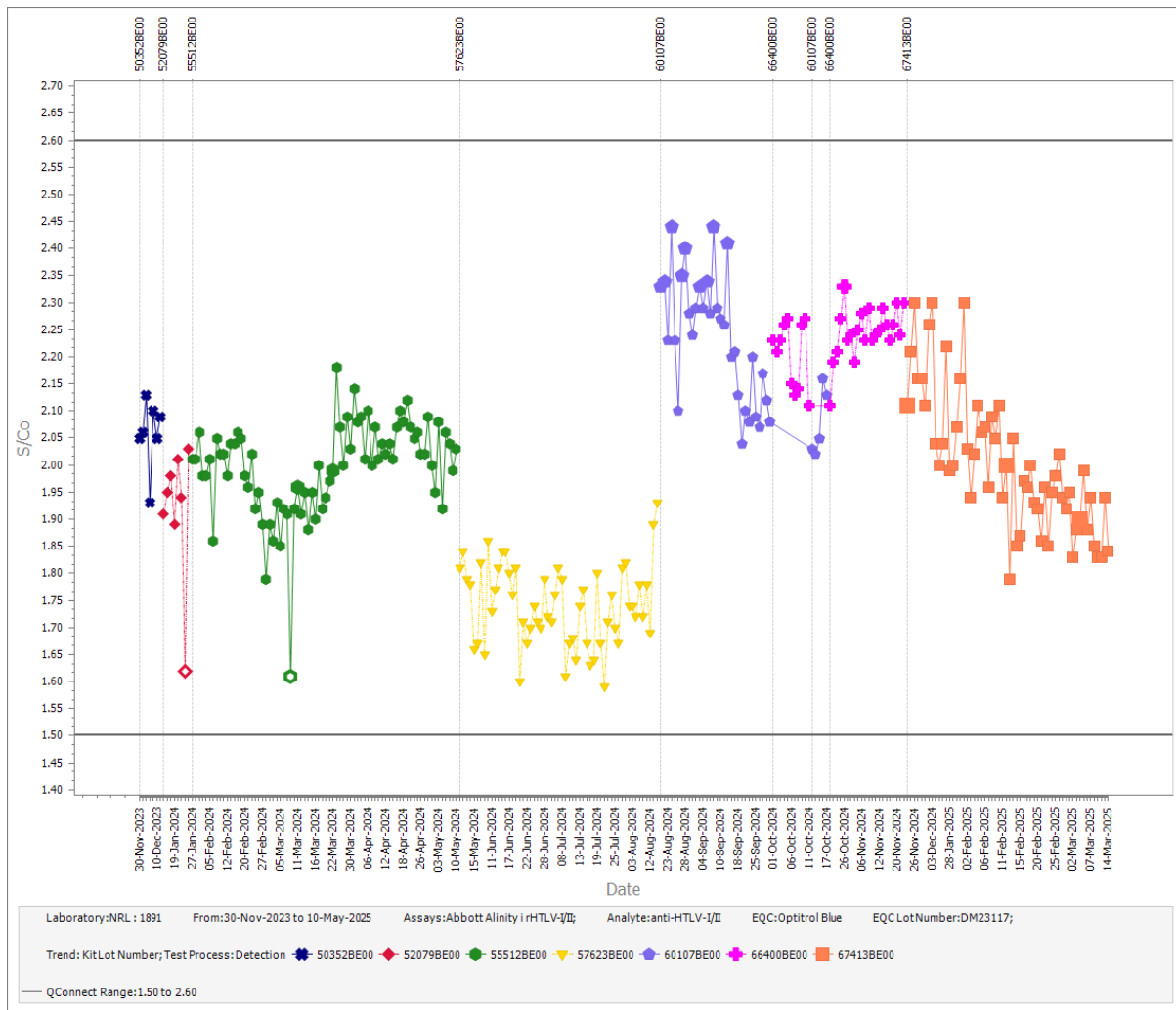


Figure 33- Participant 1891 data reported on the Abbott Alinity i rHTLV-I-II Combo assay for Optitrol Blue DM23117.

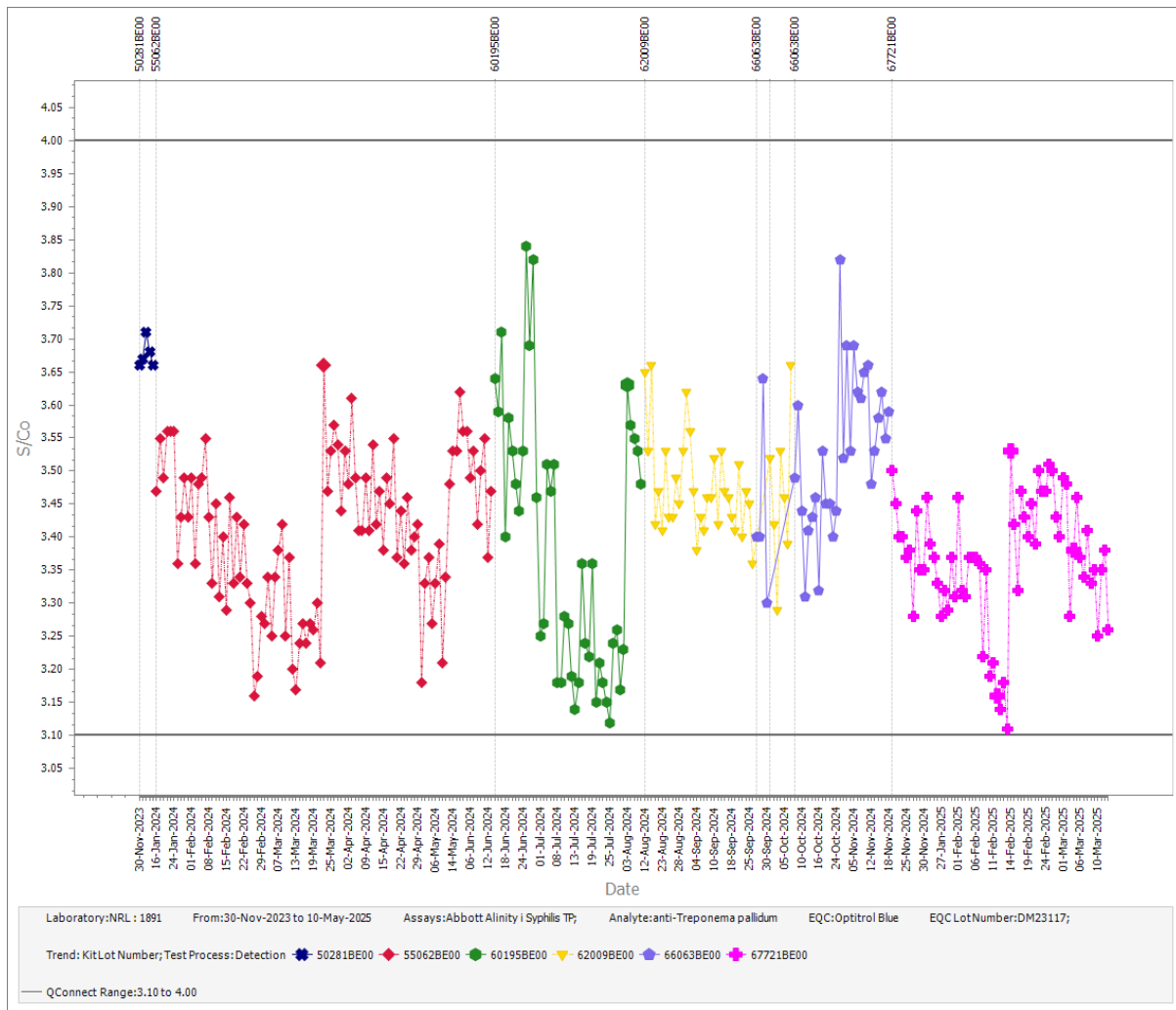


Figure 34- Participant 1891 data reported on the Abbott Alinity i Syphilis TP assay for Optitrol Blue DM23117.

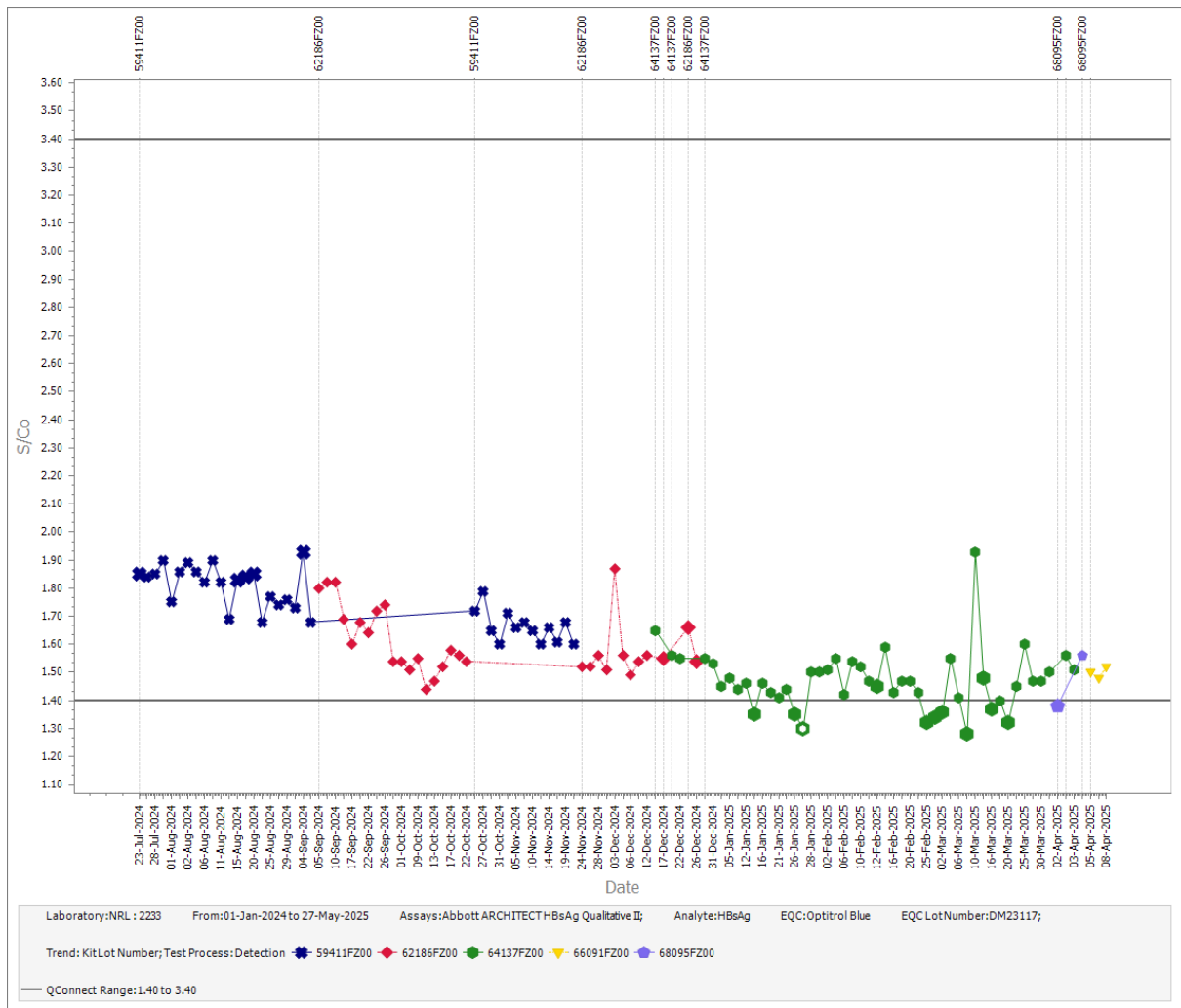


Figure 35- Participant 2233 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

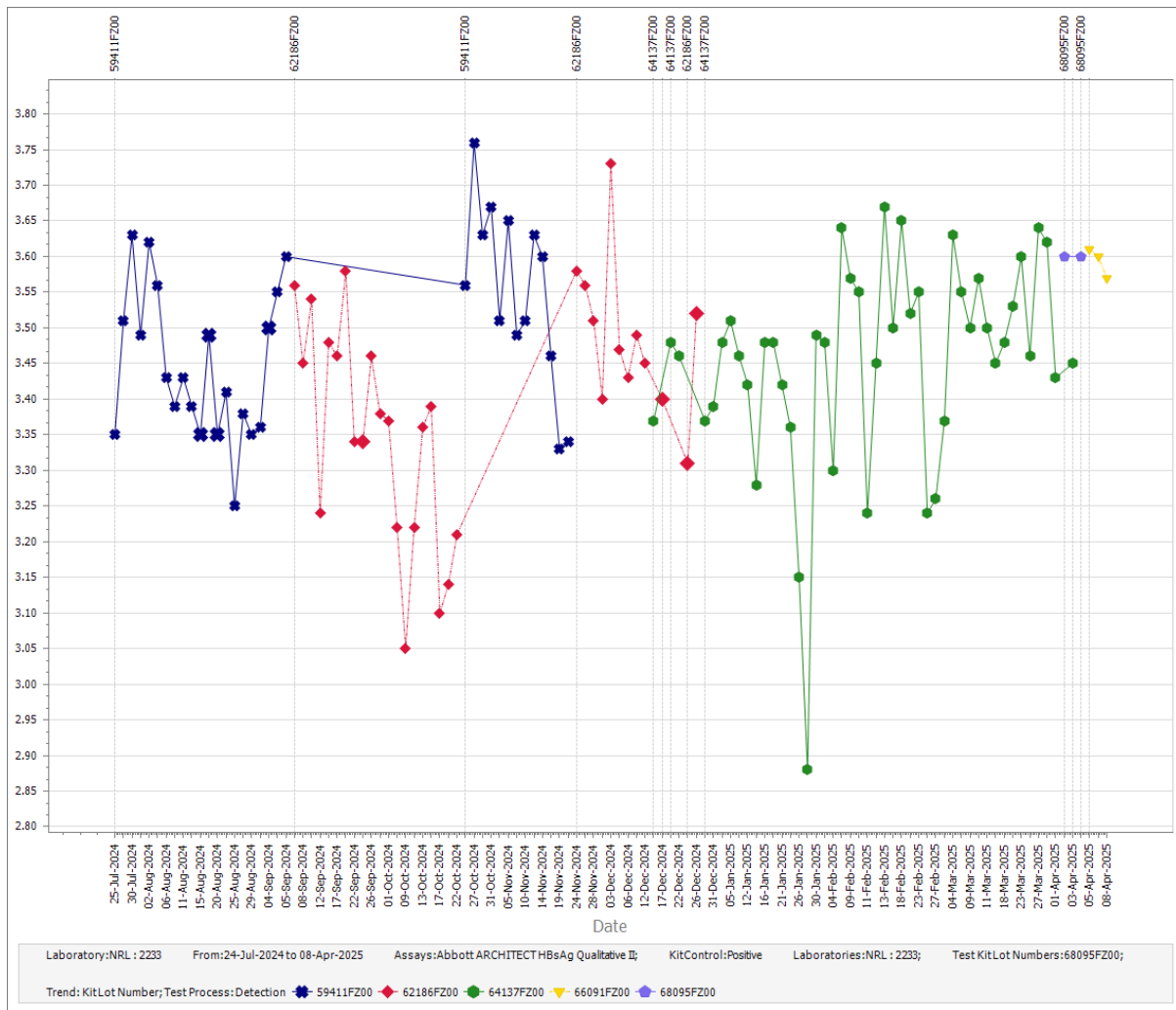


Figure 36- Participant 2233 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for the Abbott positive Kit control.

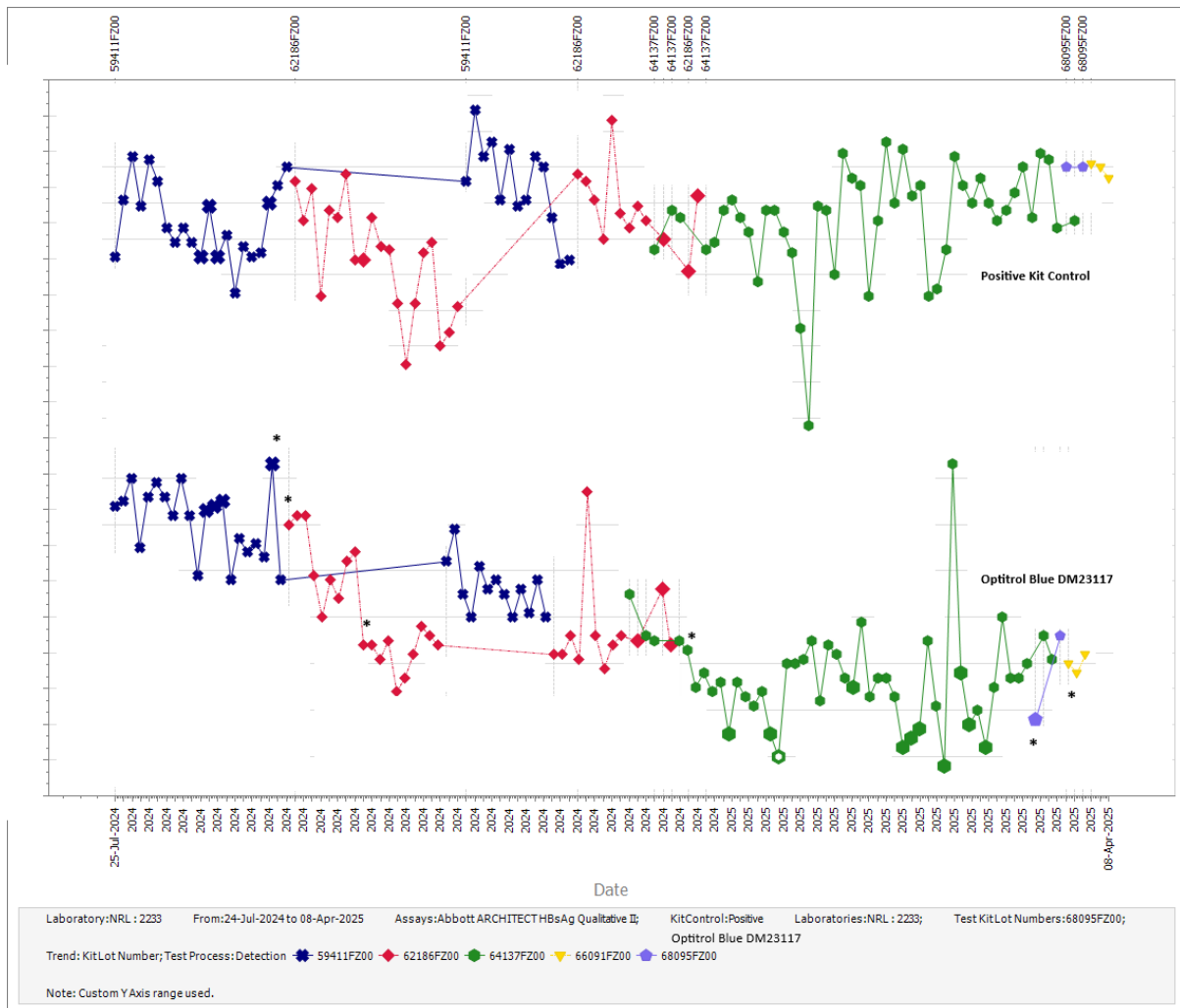


Figure 37- Comparison chart of data reported by Participant 2233 for Optitrol Blue DM23117 and Abbott Positive Kit control on the Abbott ARCHITECT HBsAg Qualitative II assay.

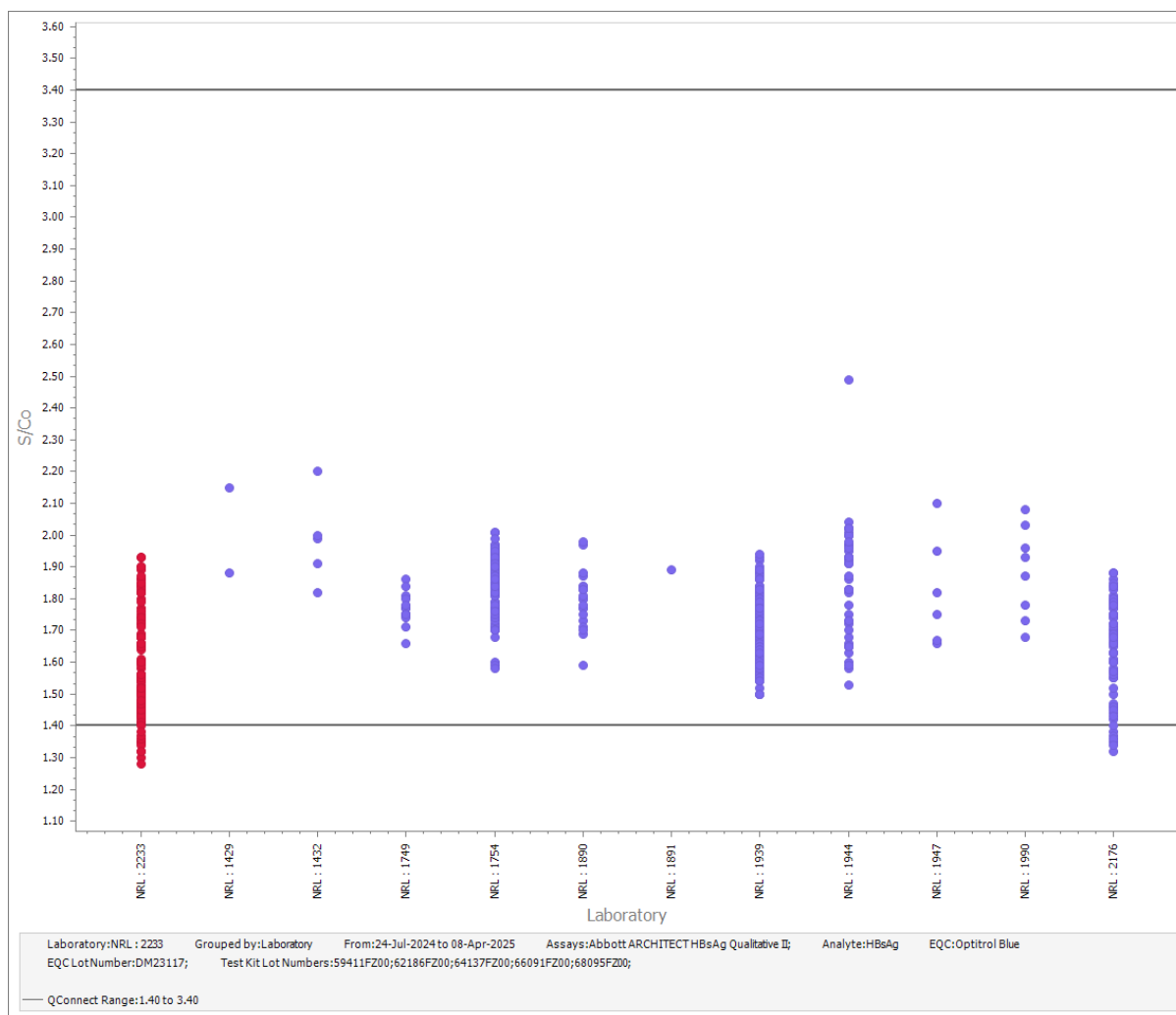


Figure 38- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by participant, for reagent lots in use by Participant 2233.

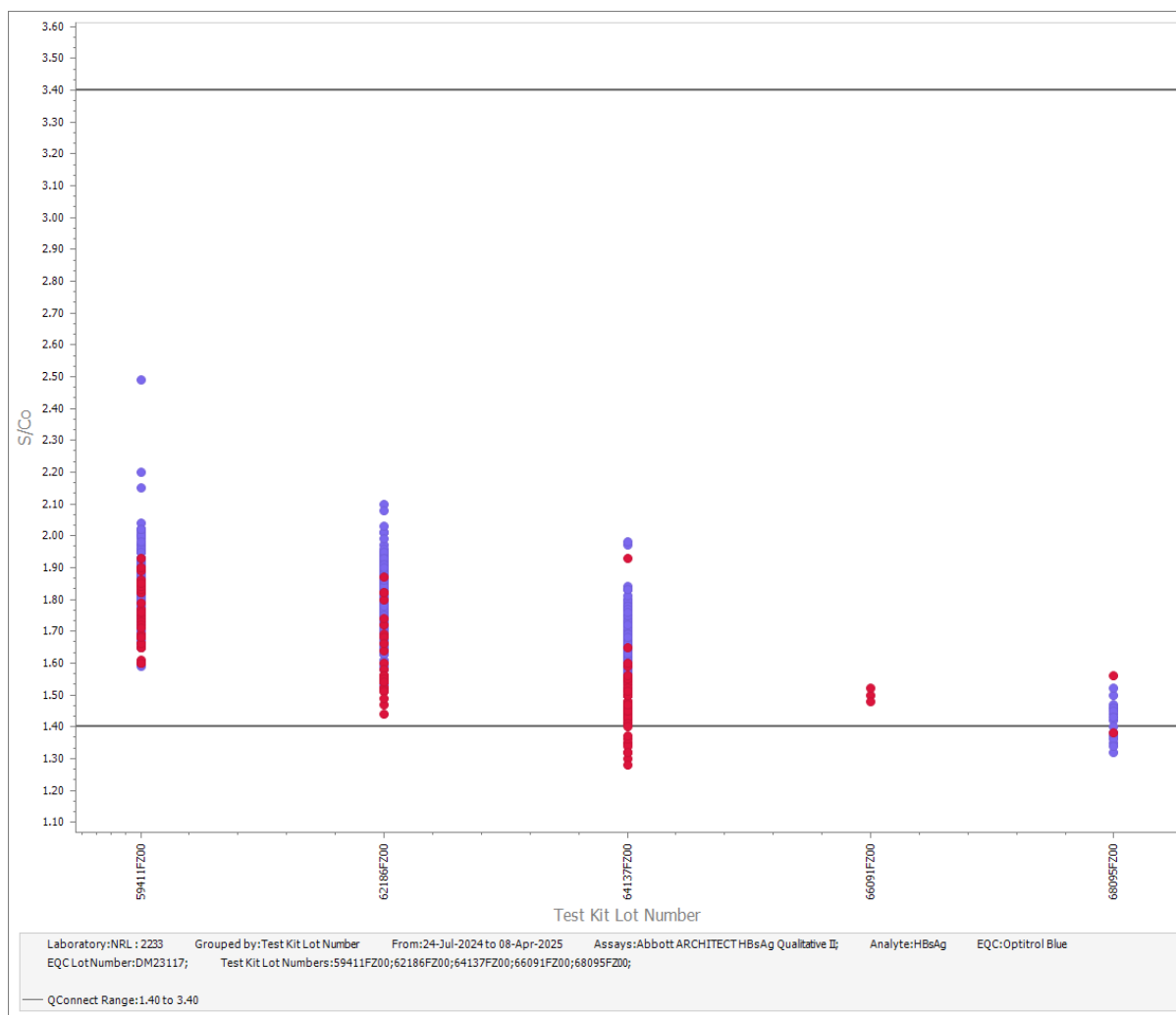


Figure 39- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 2233.

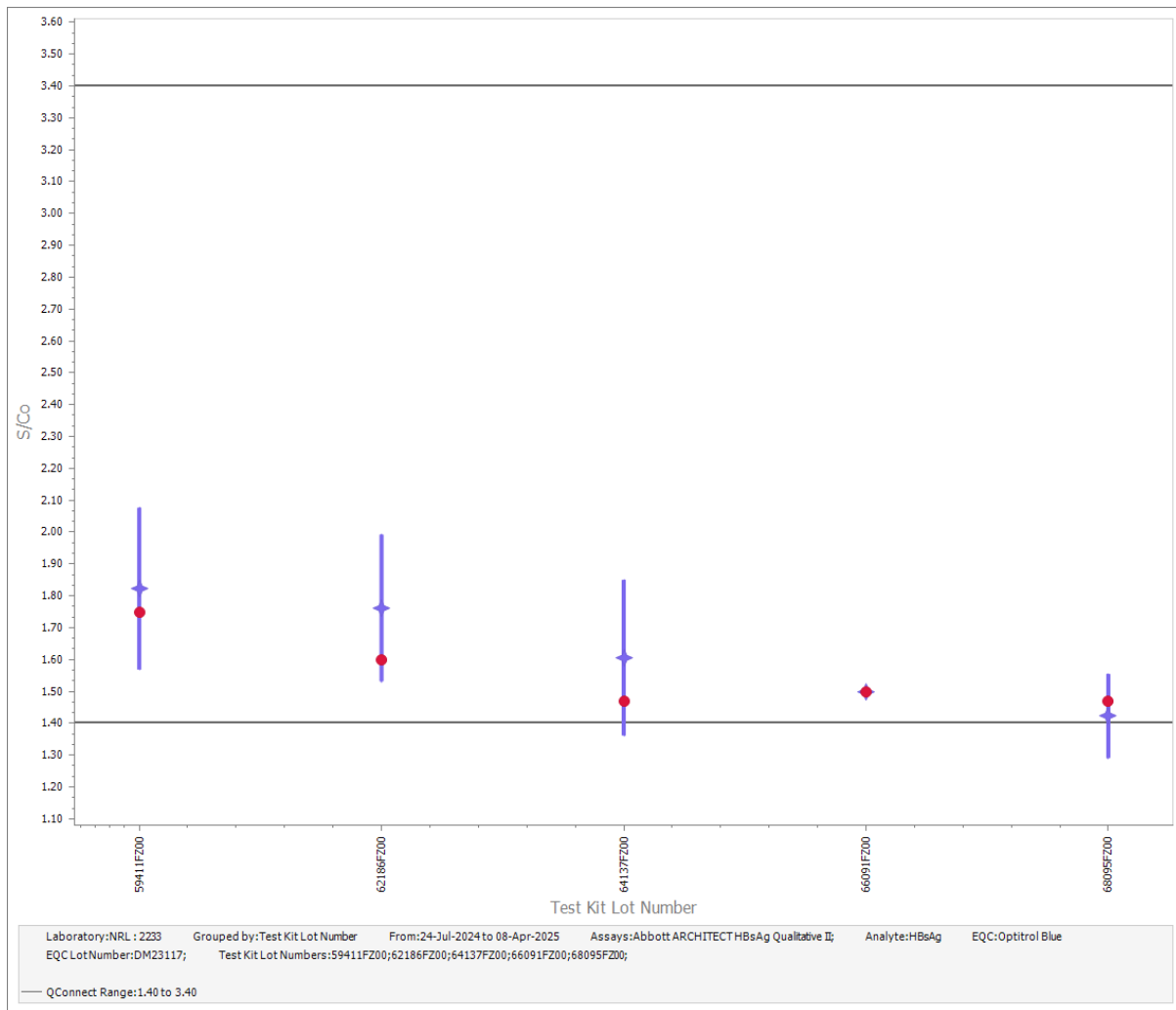


Figure 40- Peer group data and mean S/Co values reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for reagent lots in use by Participant 2233.

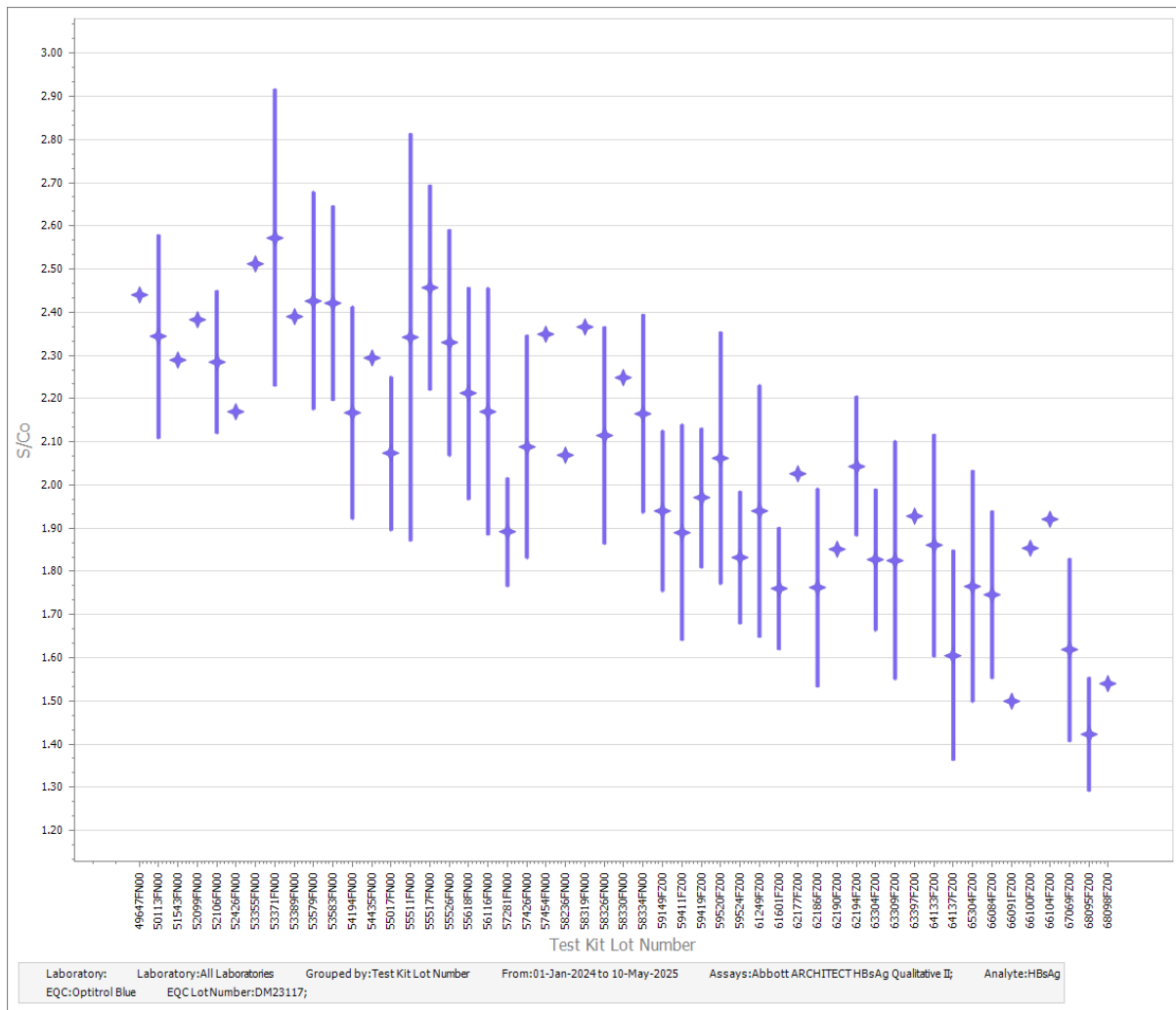


Figure 41- Peer group data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117 by reagent lot, for all reagent lots in use across the peer group from 01 January through 10 March 2025.

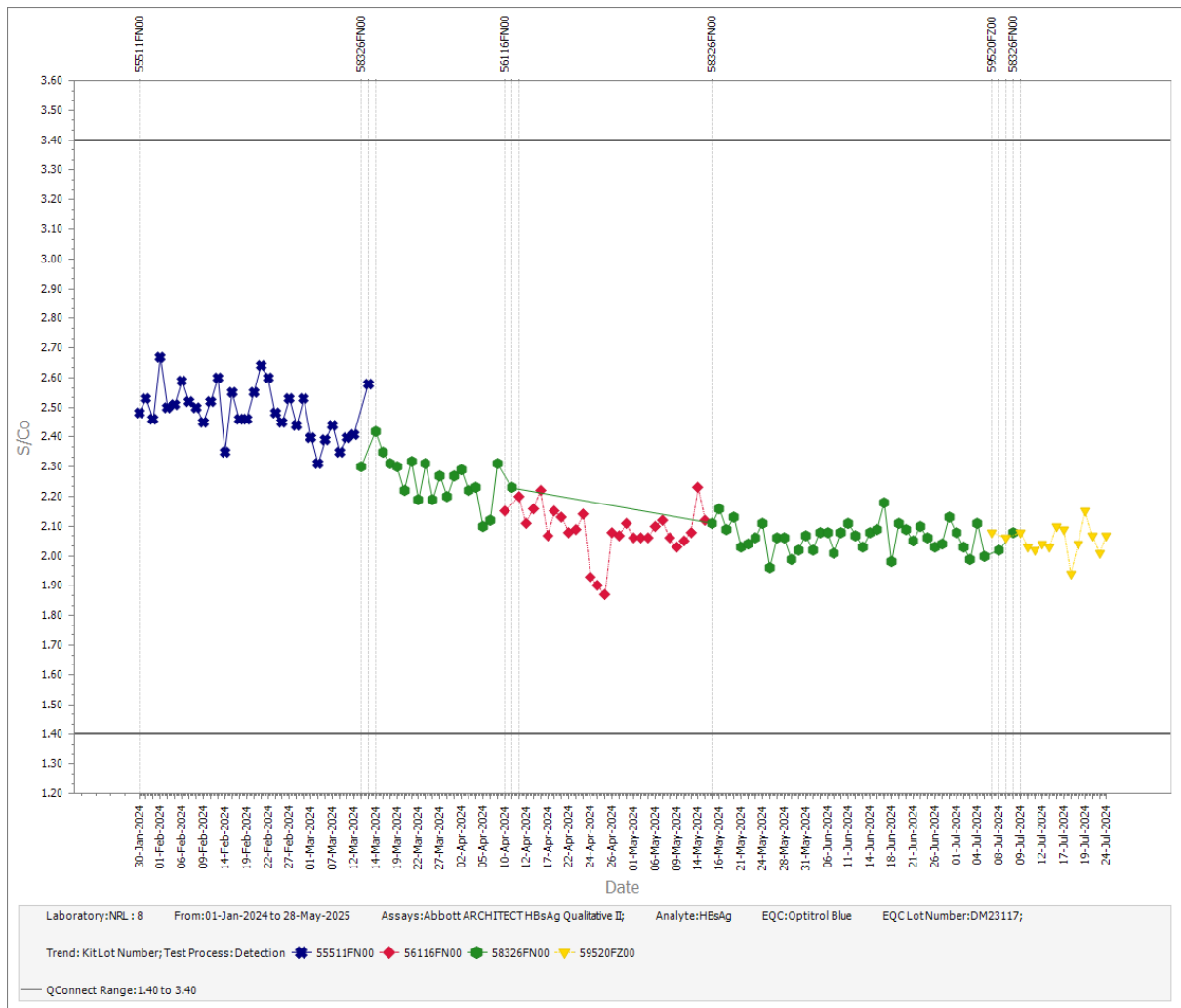


Figure 42- Participant 8 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

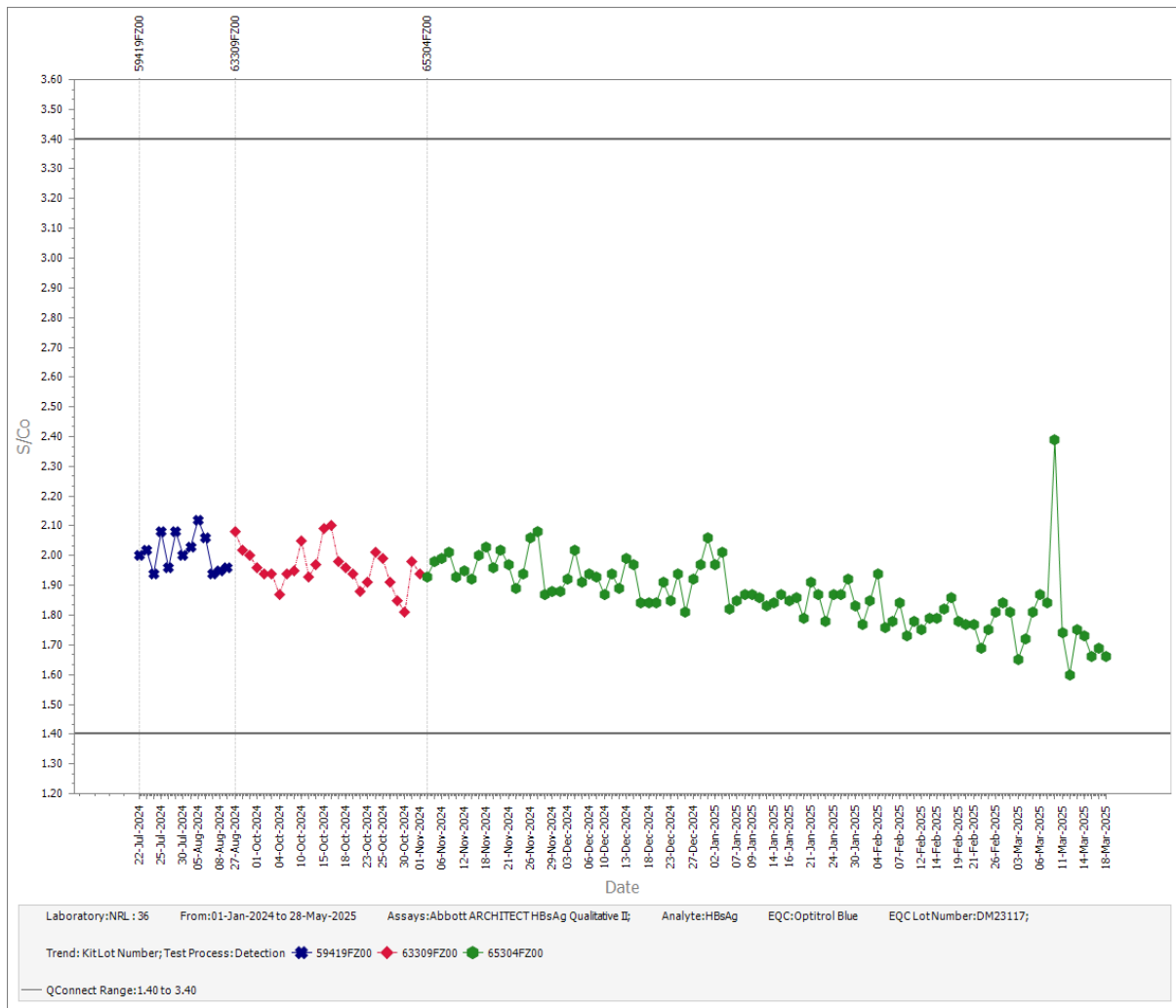
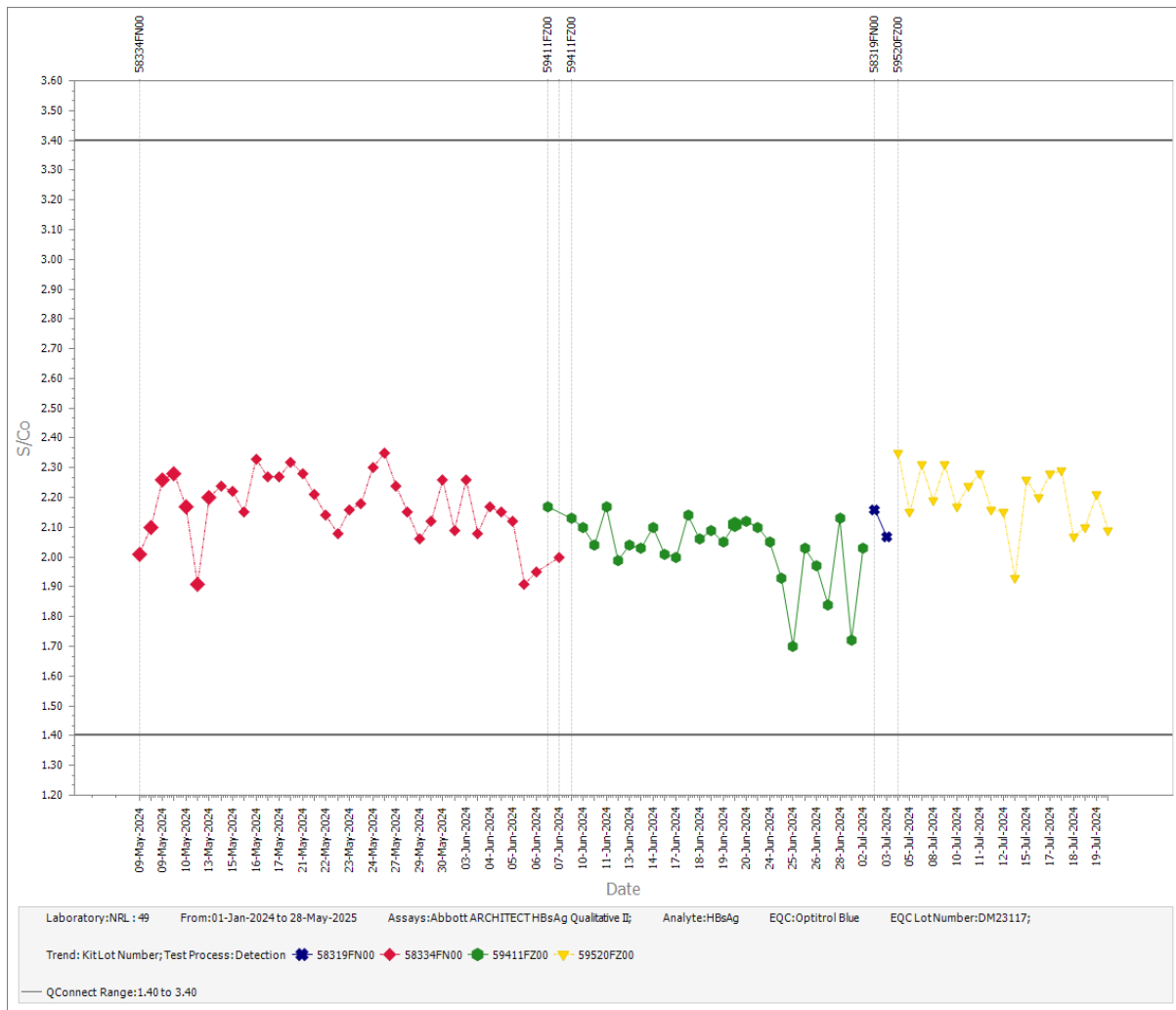


Figure 43- Participant 36 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.



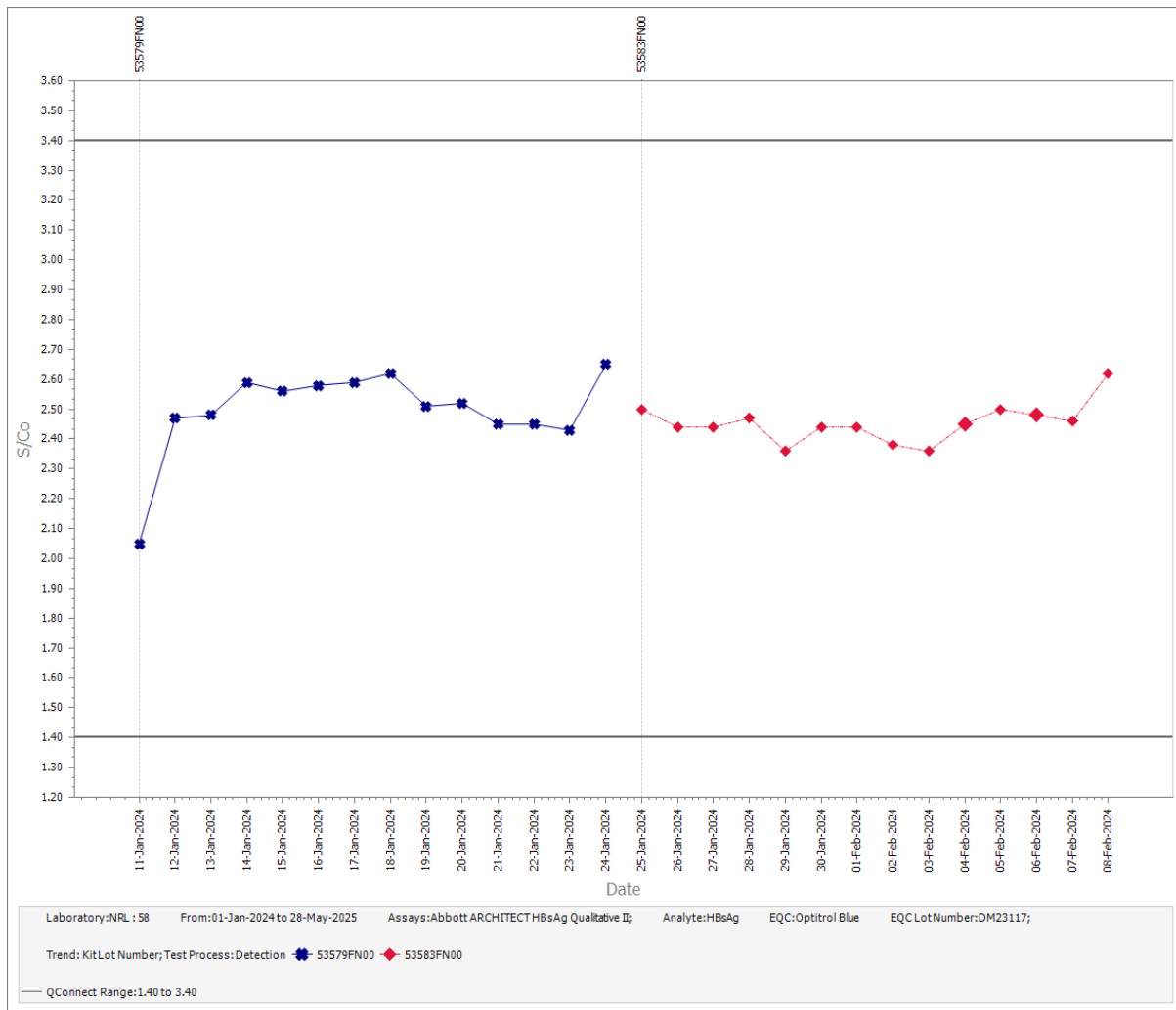


Figure 45-Participant 58 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

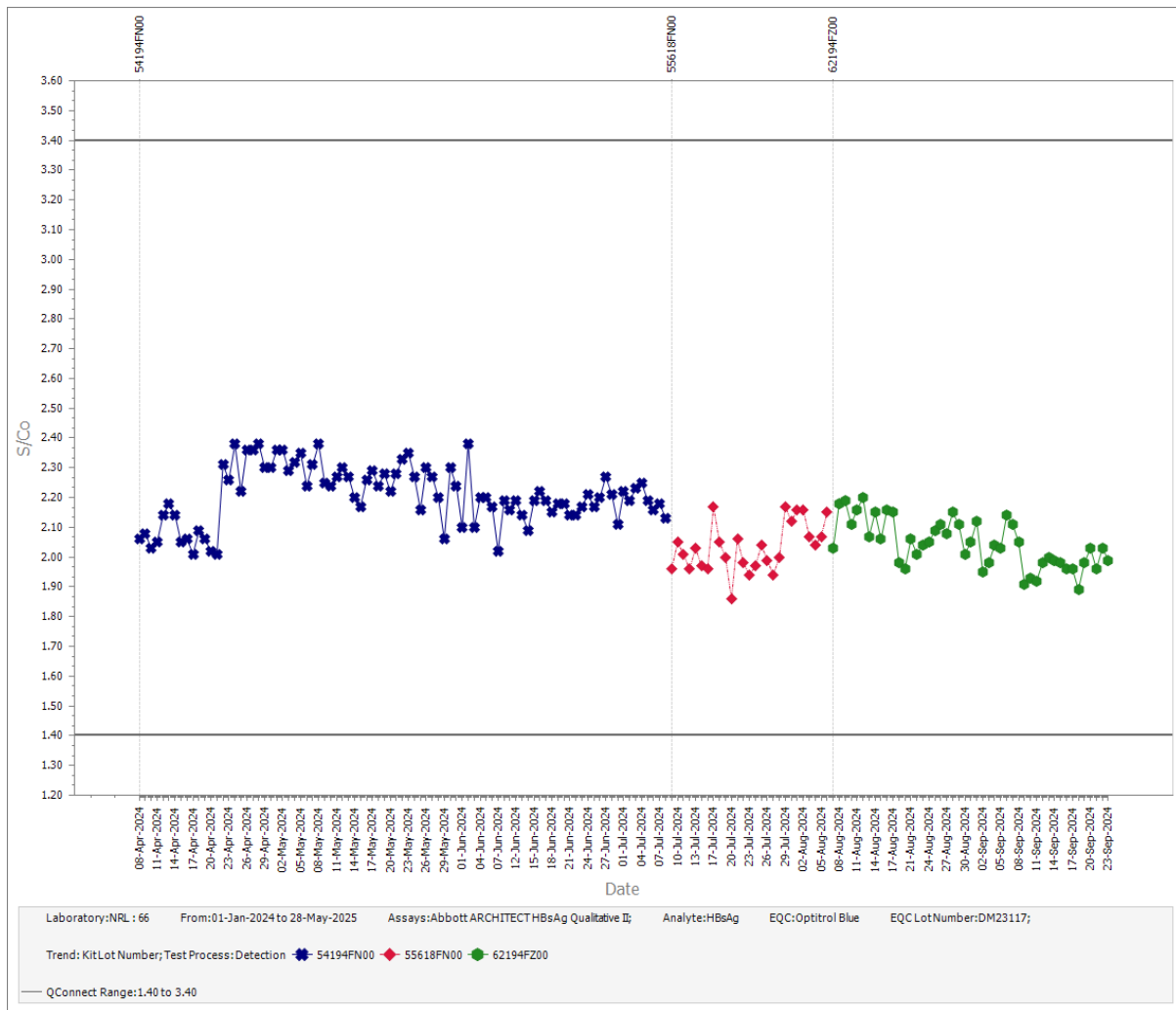


Figure 46- Participant 66 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

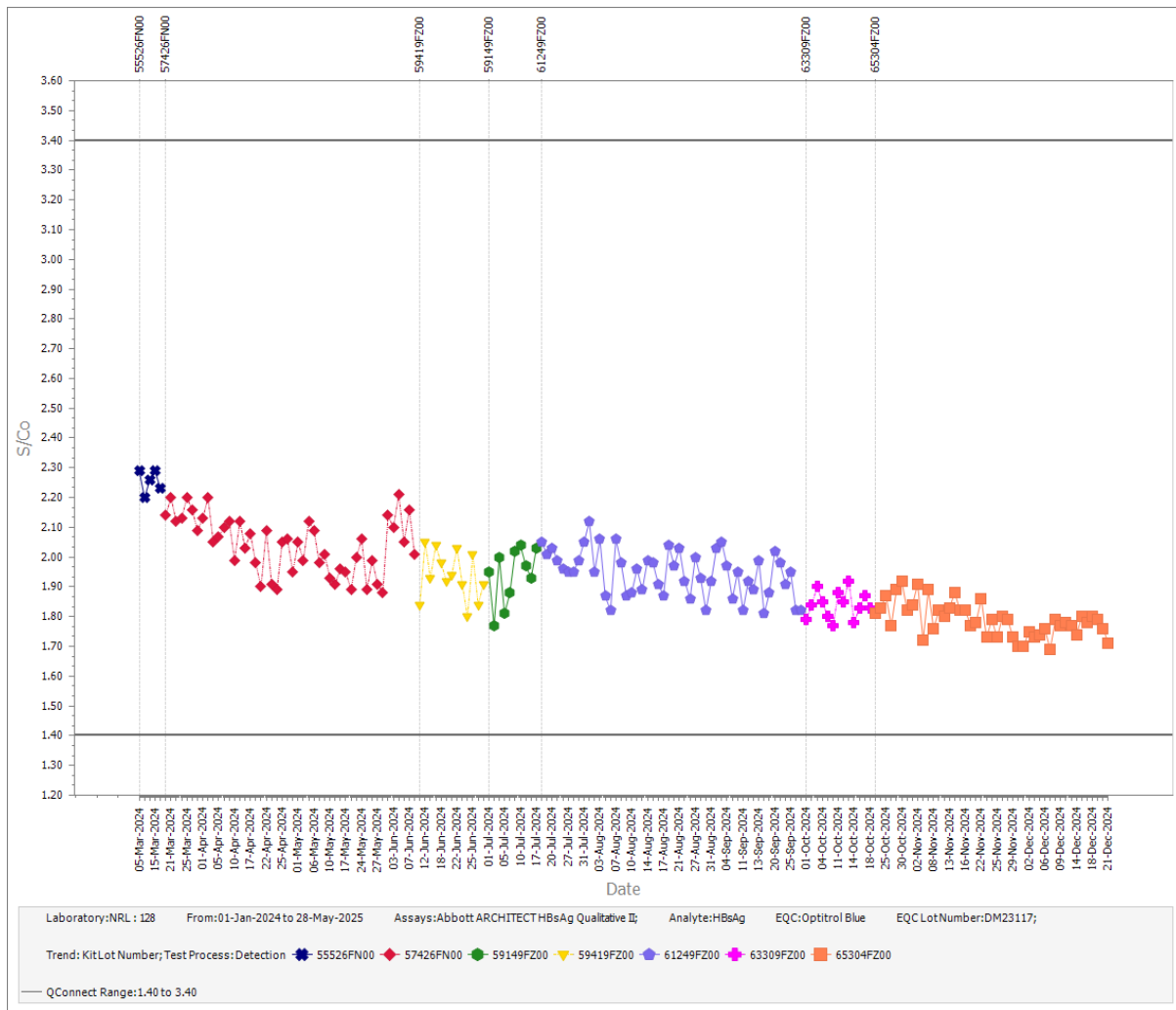


Figure 47- Participant 128 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

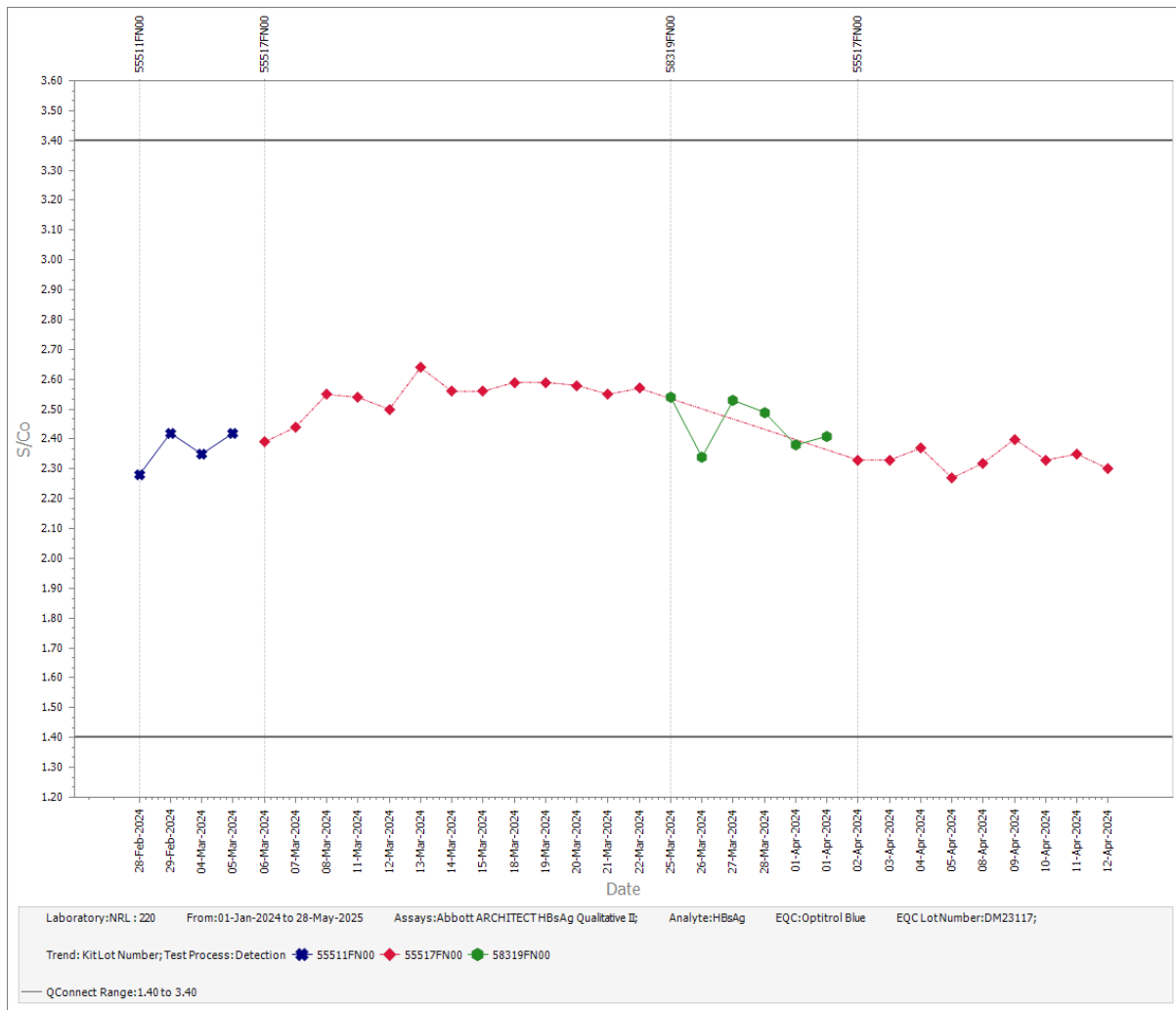
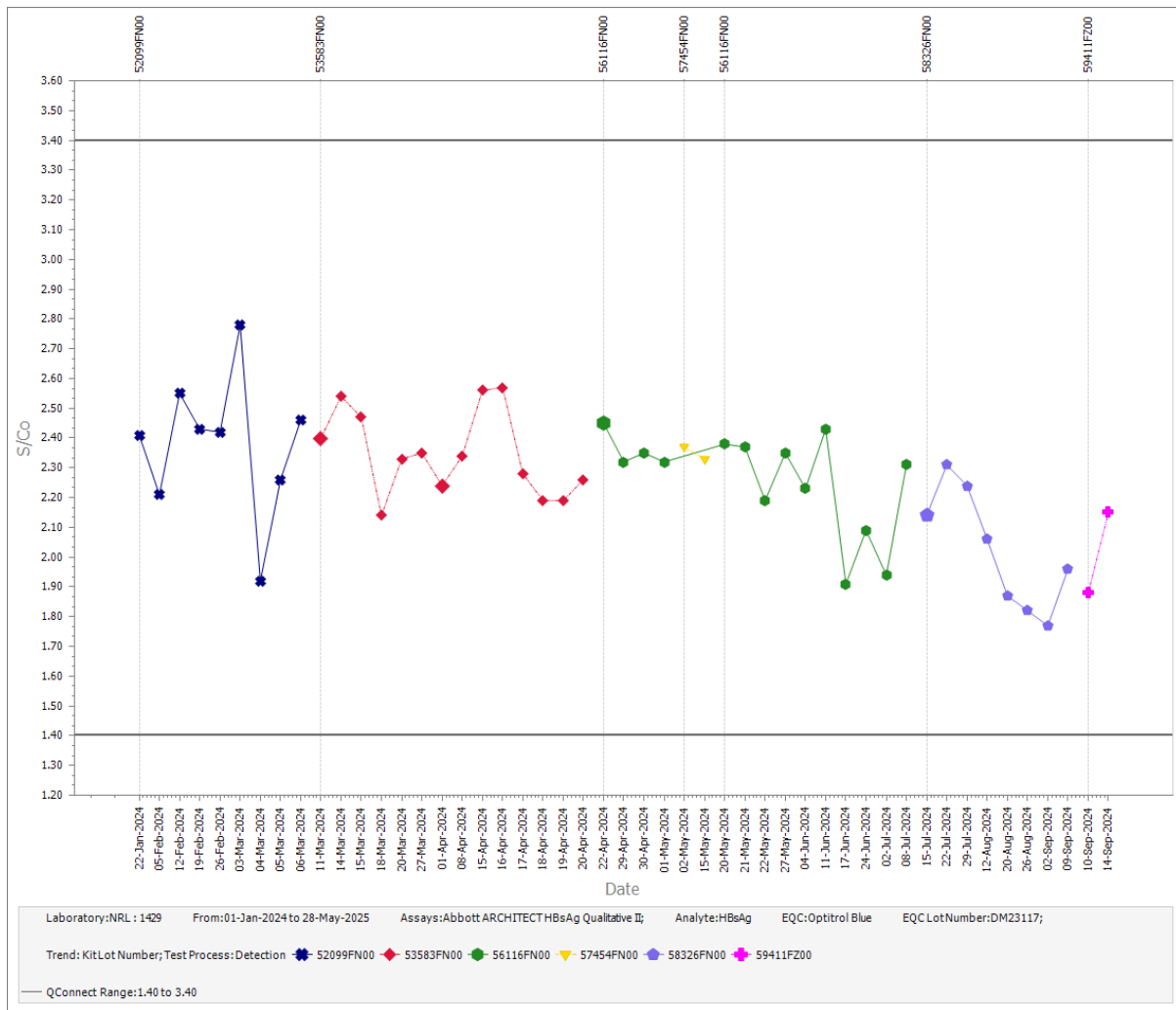
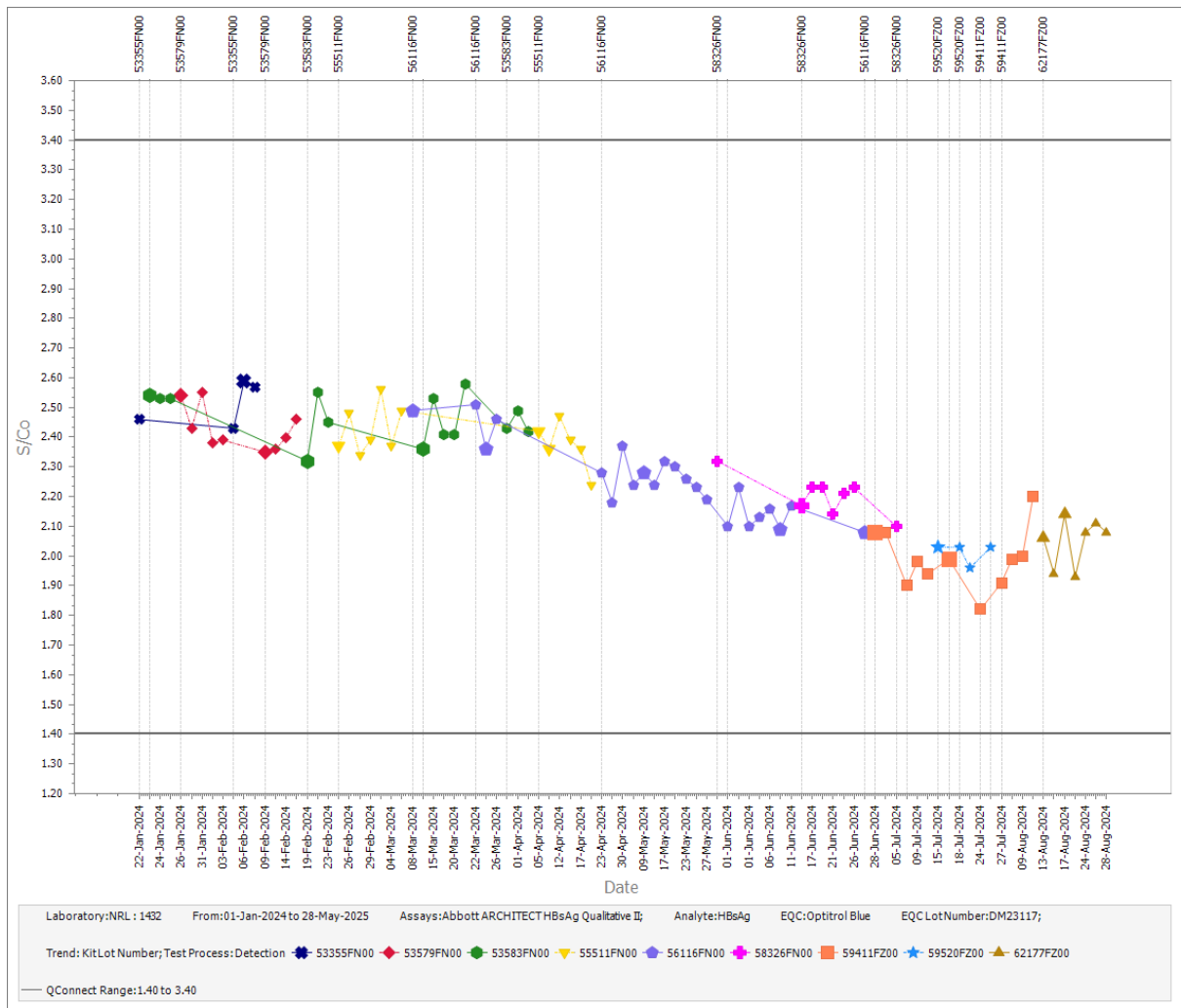


Figure 48- Participant 220 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.





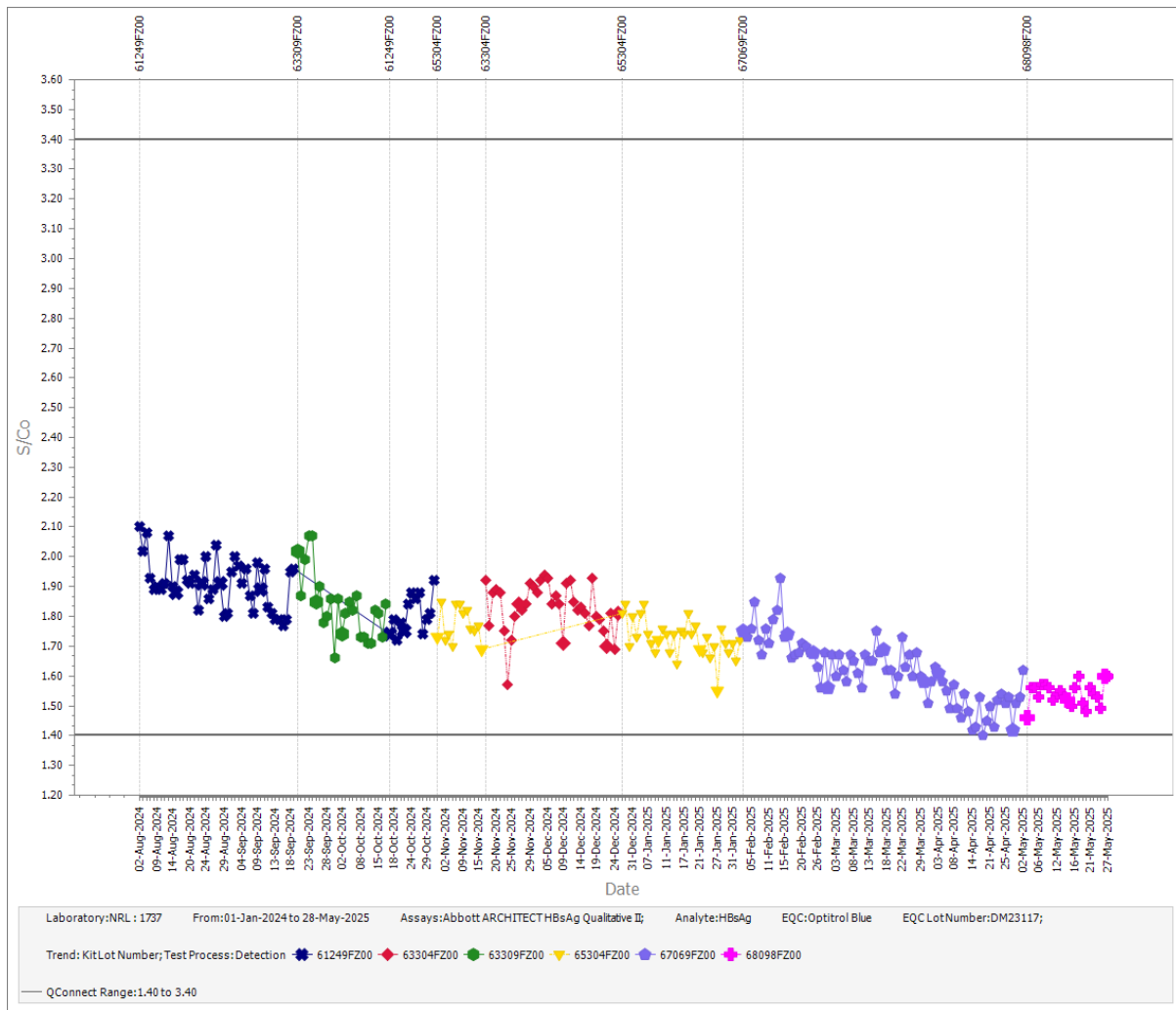


Figure 52- Participant 1737 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

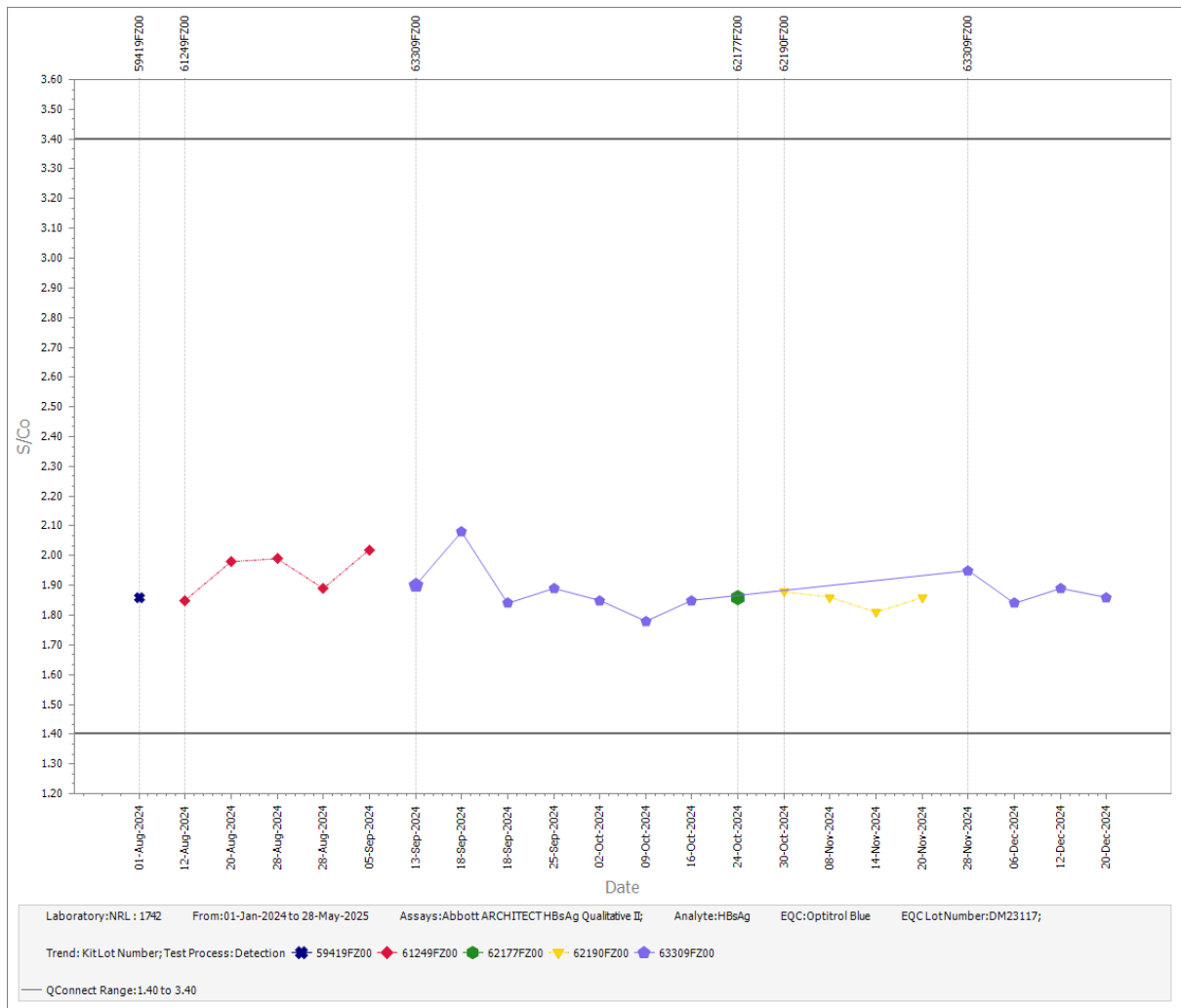
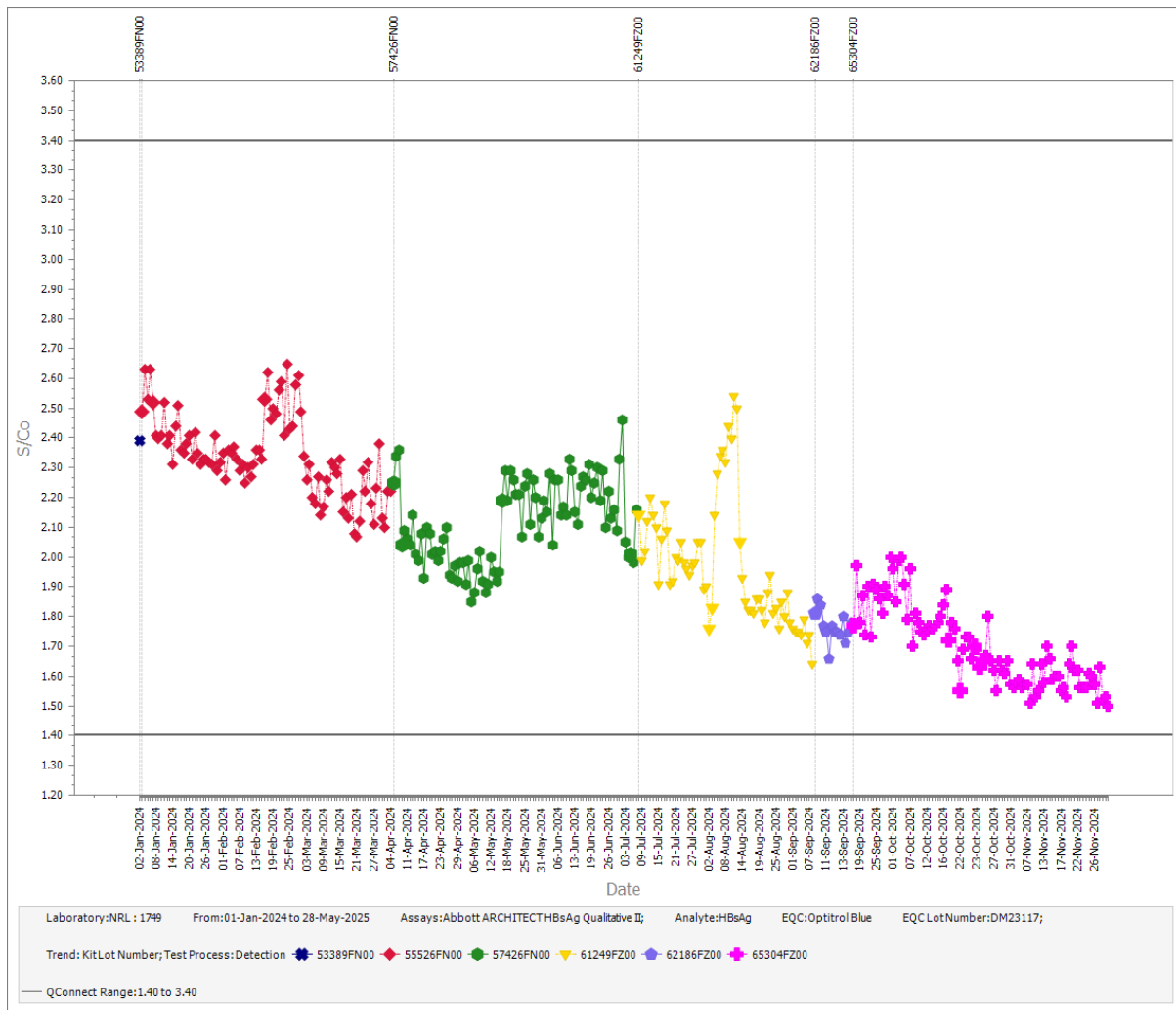
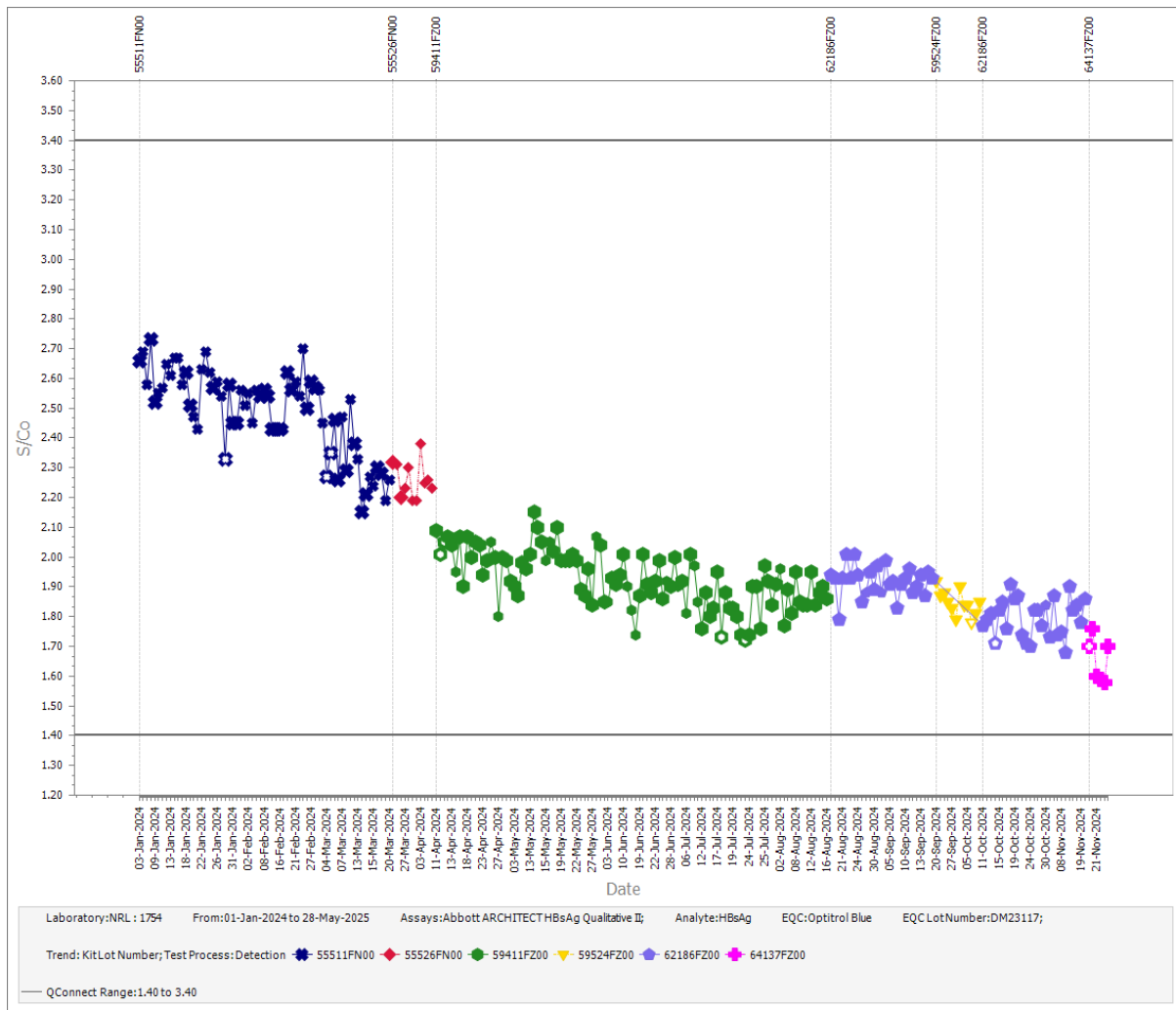


Figure 53- Participant 1742 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.





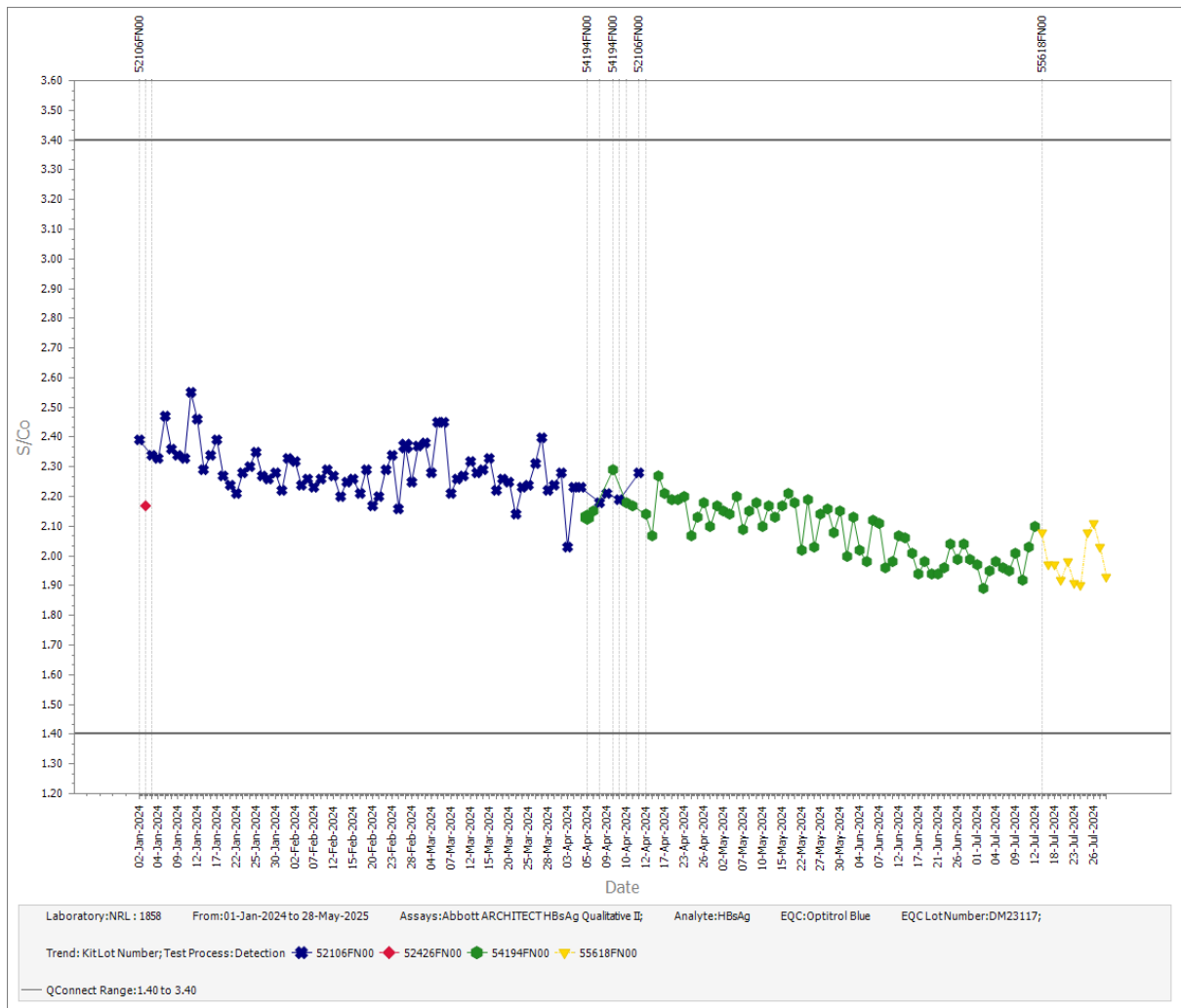


Figure 56- Participant 1858 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

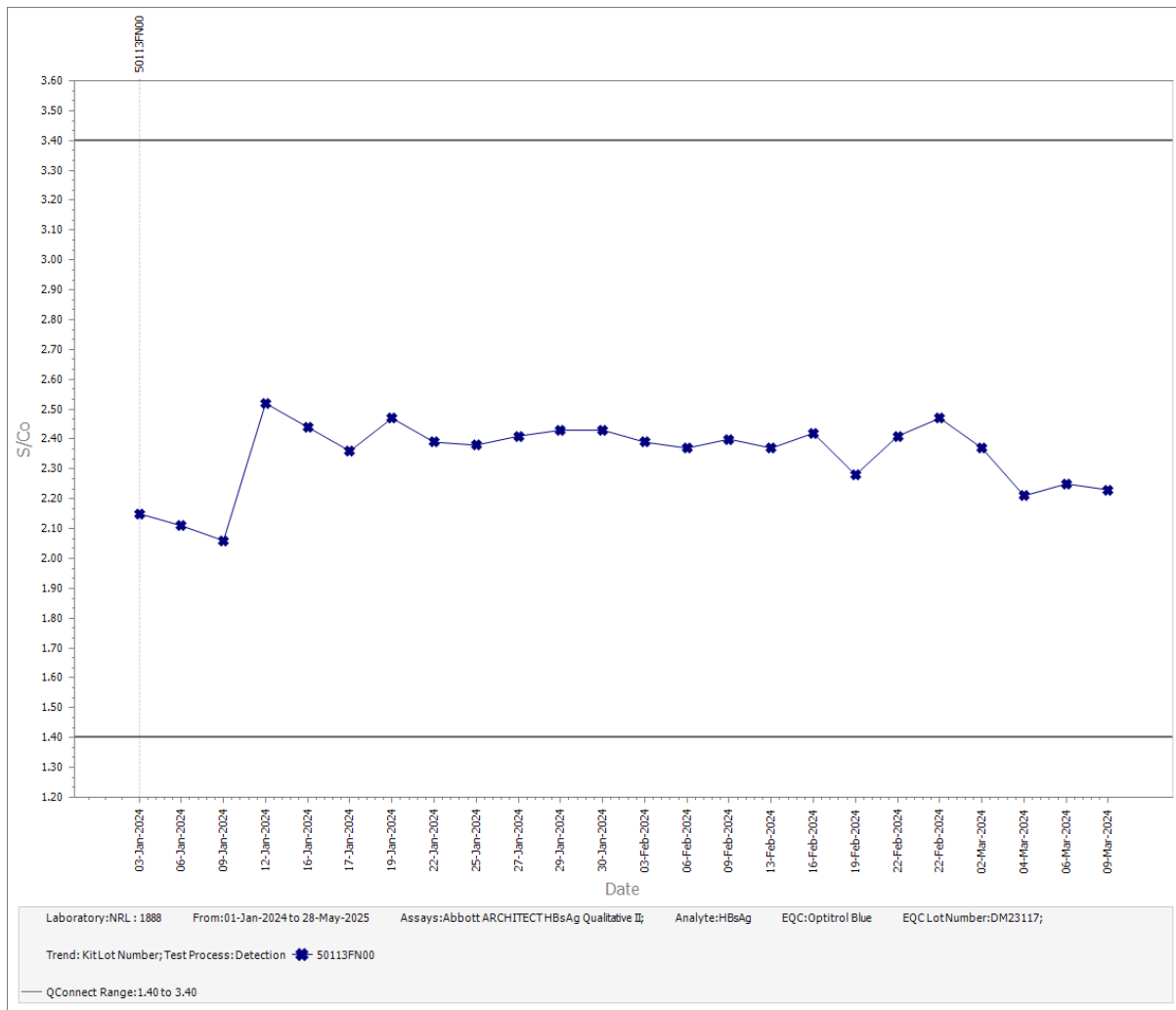


Figure 57- Participant 1888 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

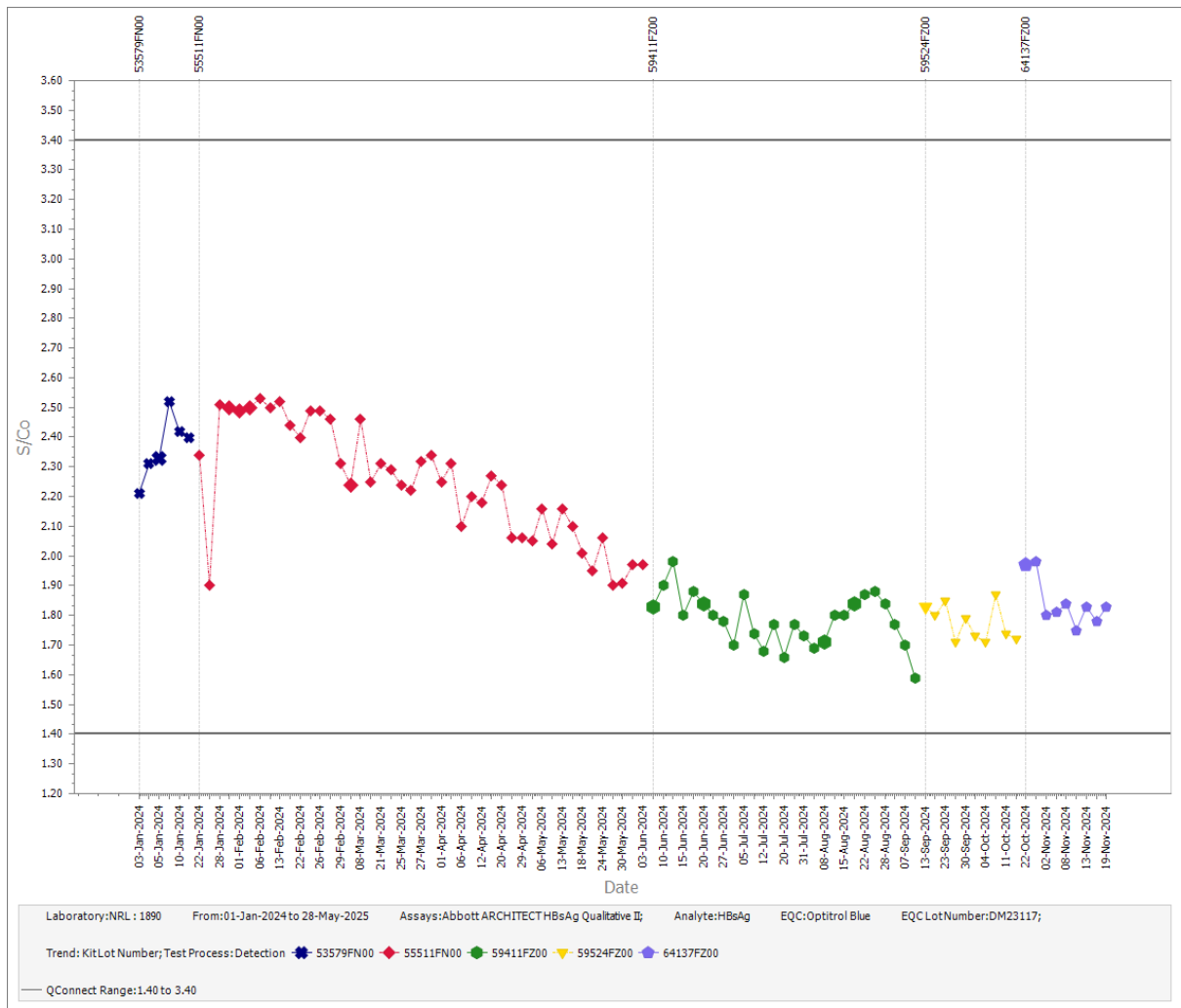


Figure 58- Participant 1890 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

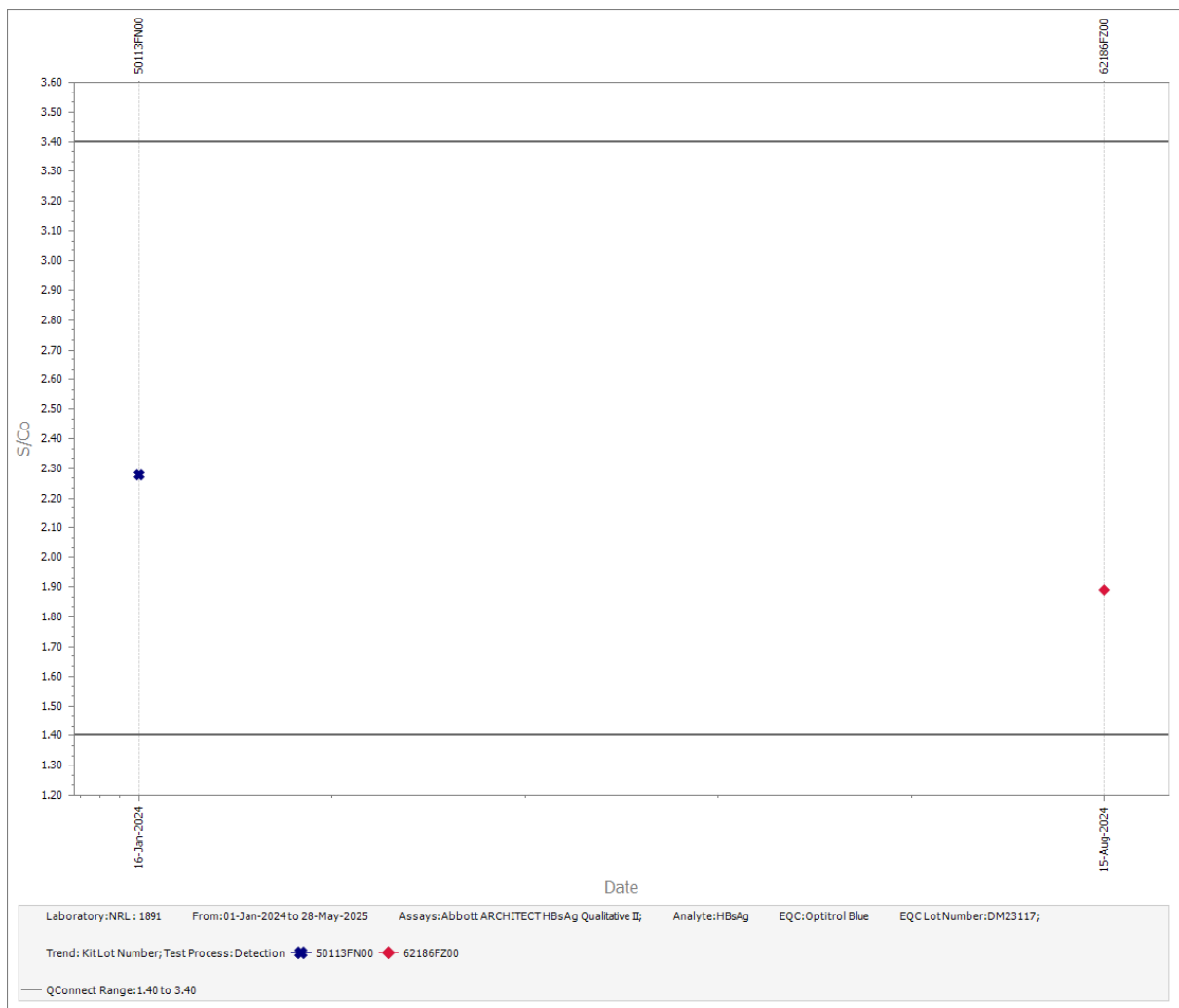


Figure 59- Participant 1891 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

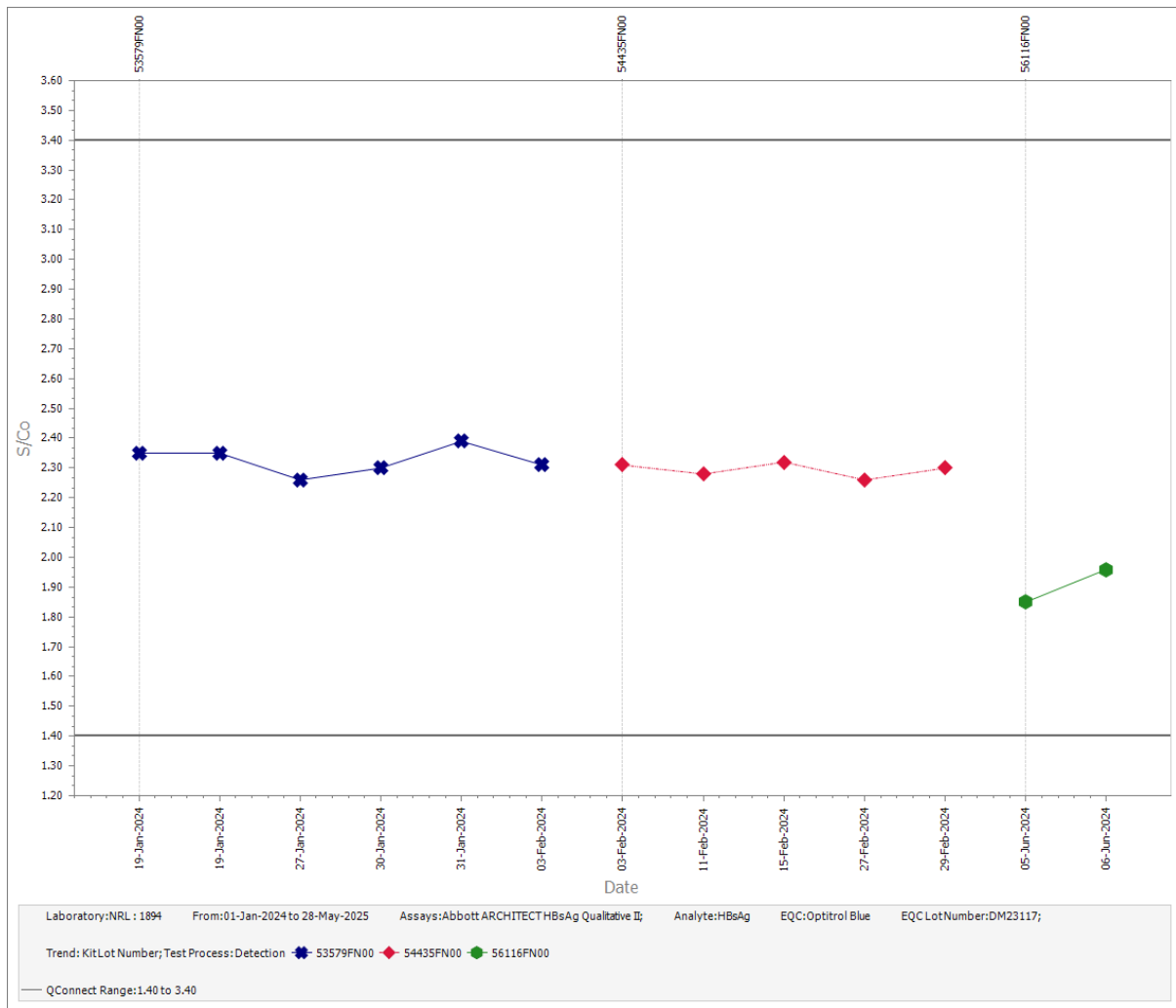
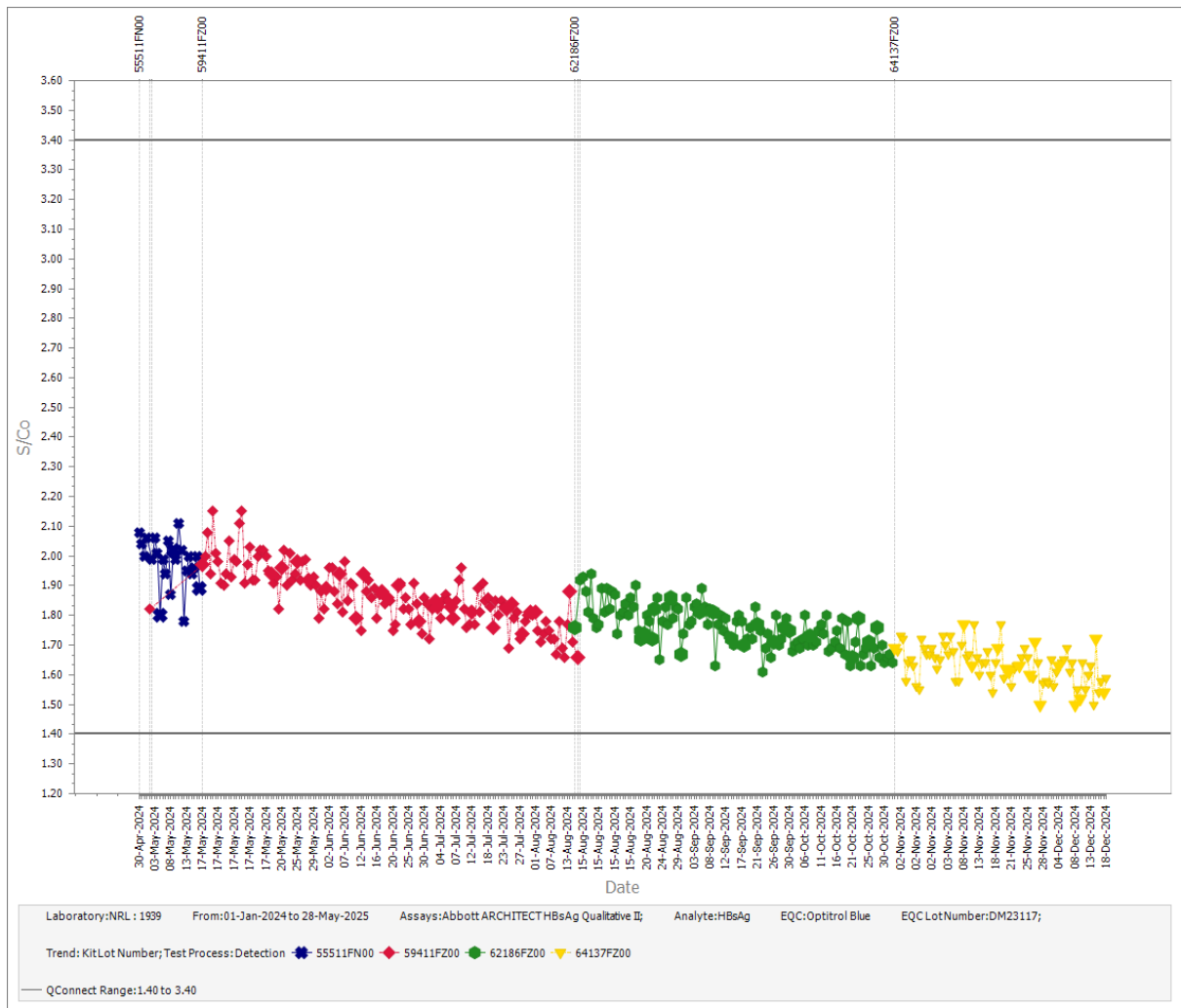


Figure 60- Participant 1894 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.



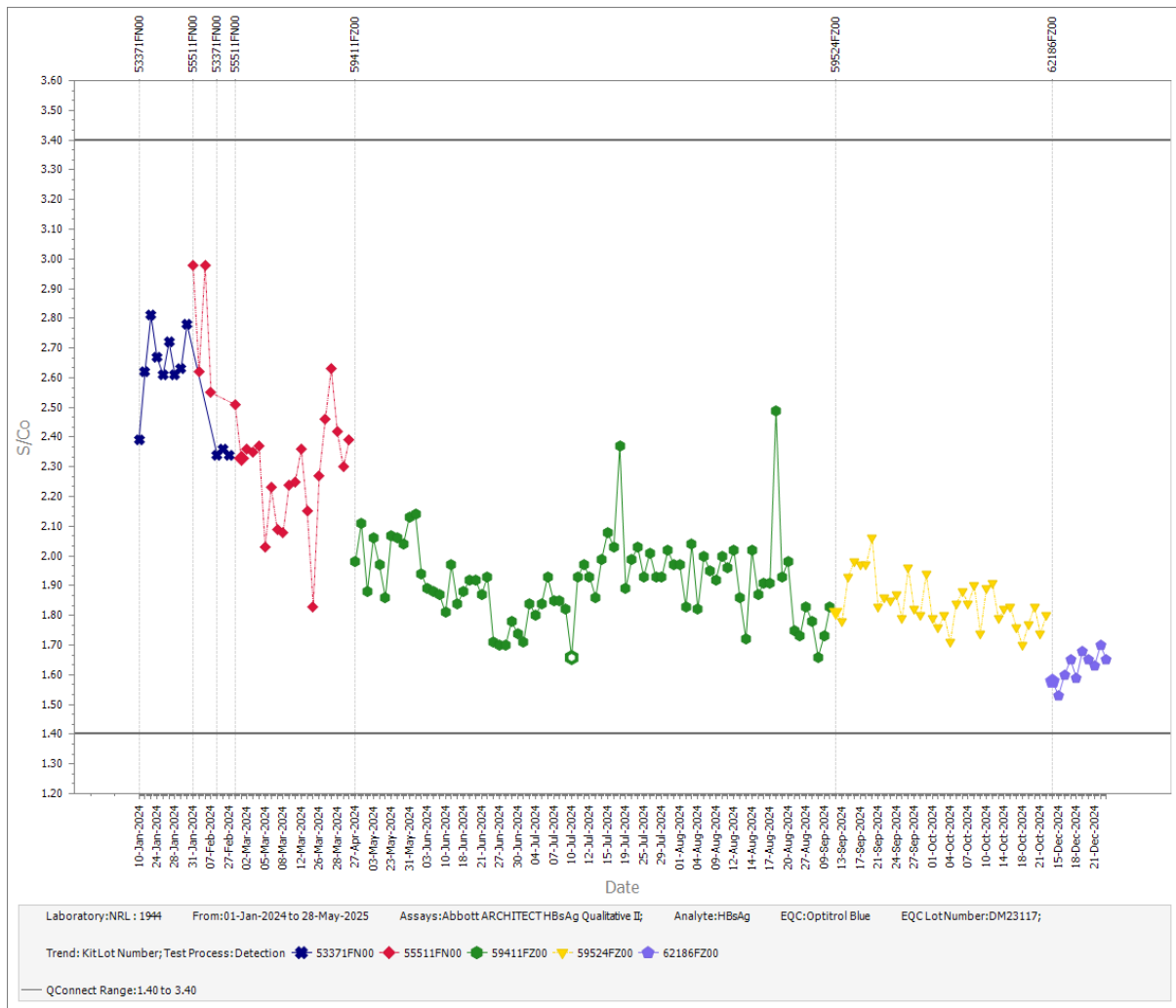


Figure 62- Participant 1944 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

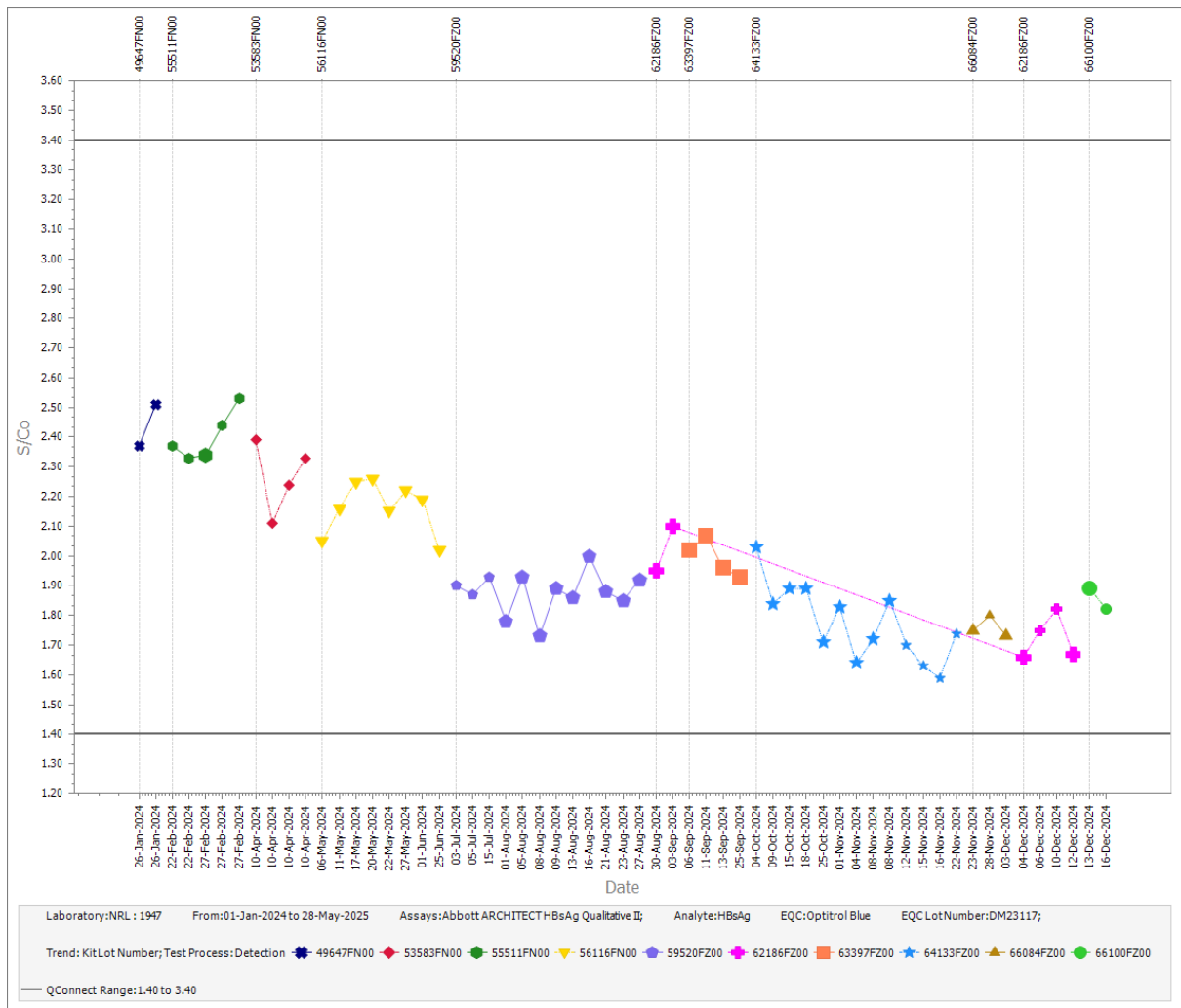
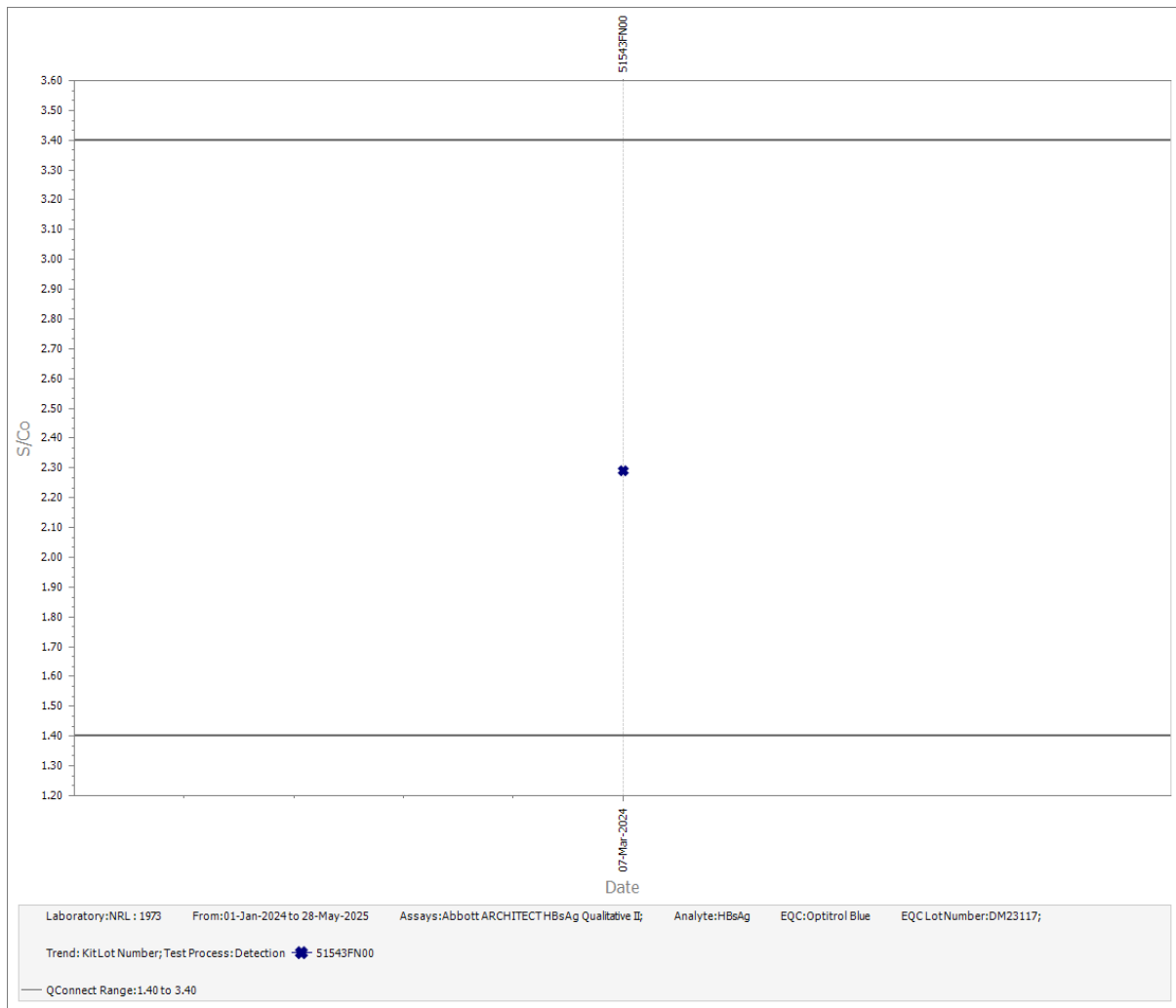


Figure 63- Participant 1947 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.



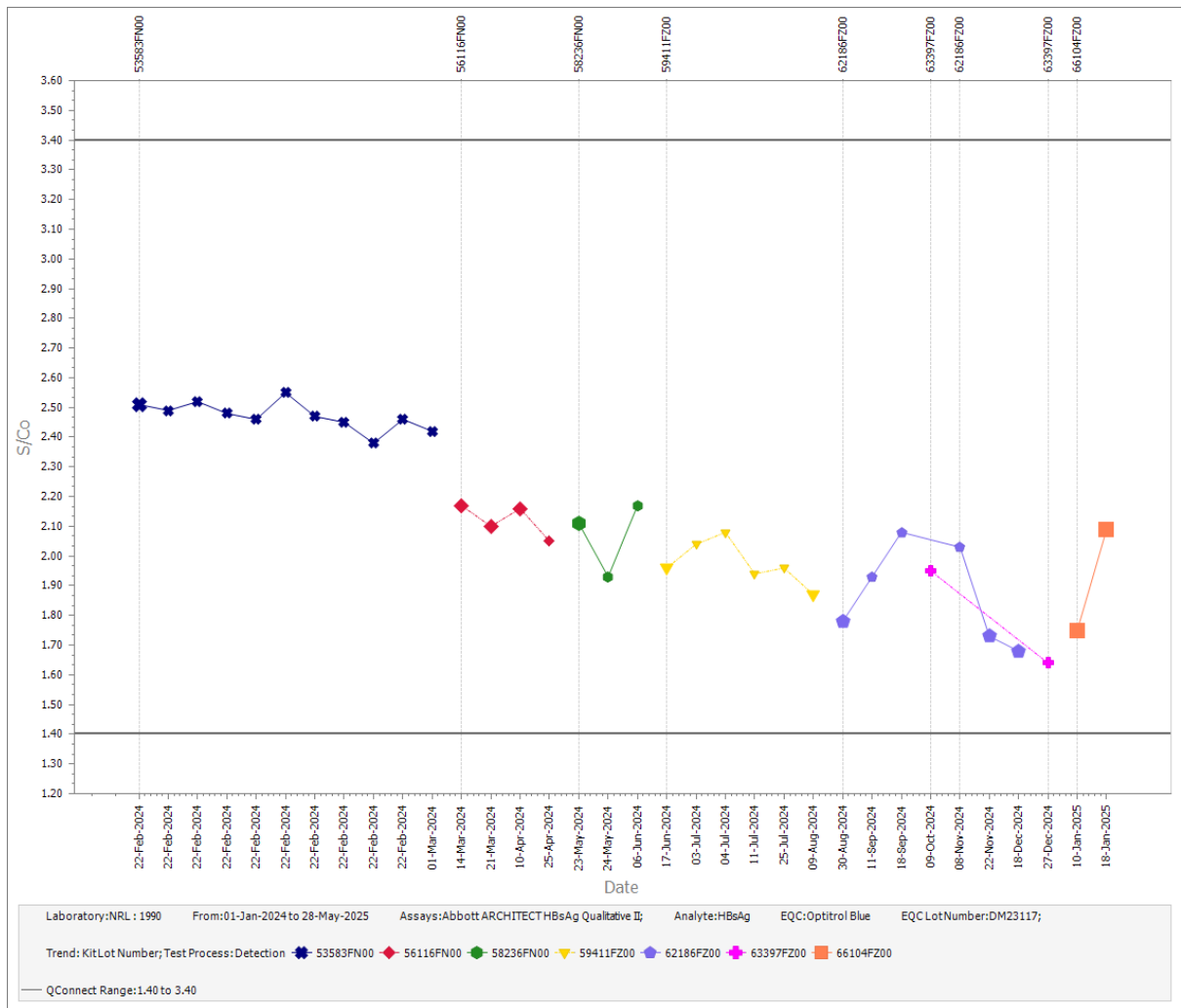


Figure 65- Participant 1990 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

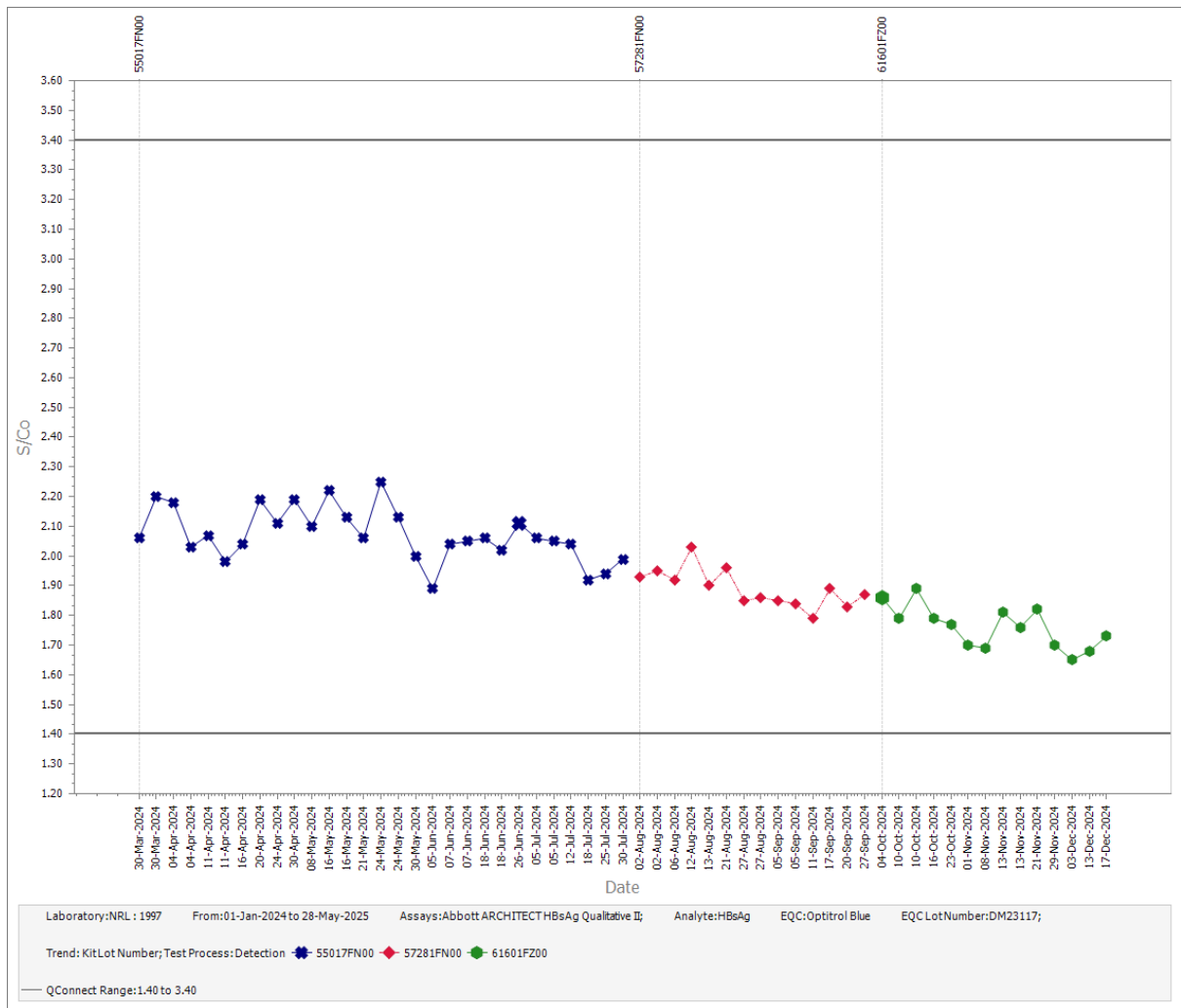


Figure 66- Participant 1997 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

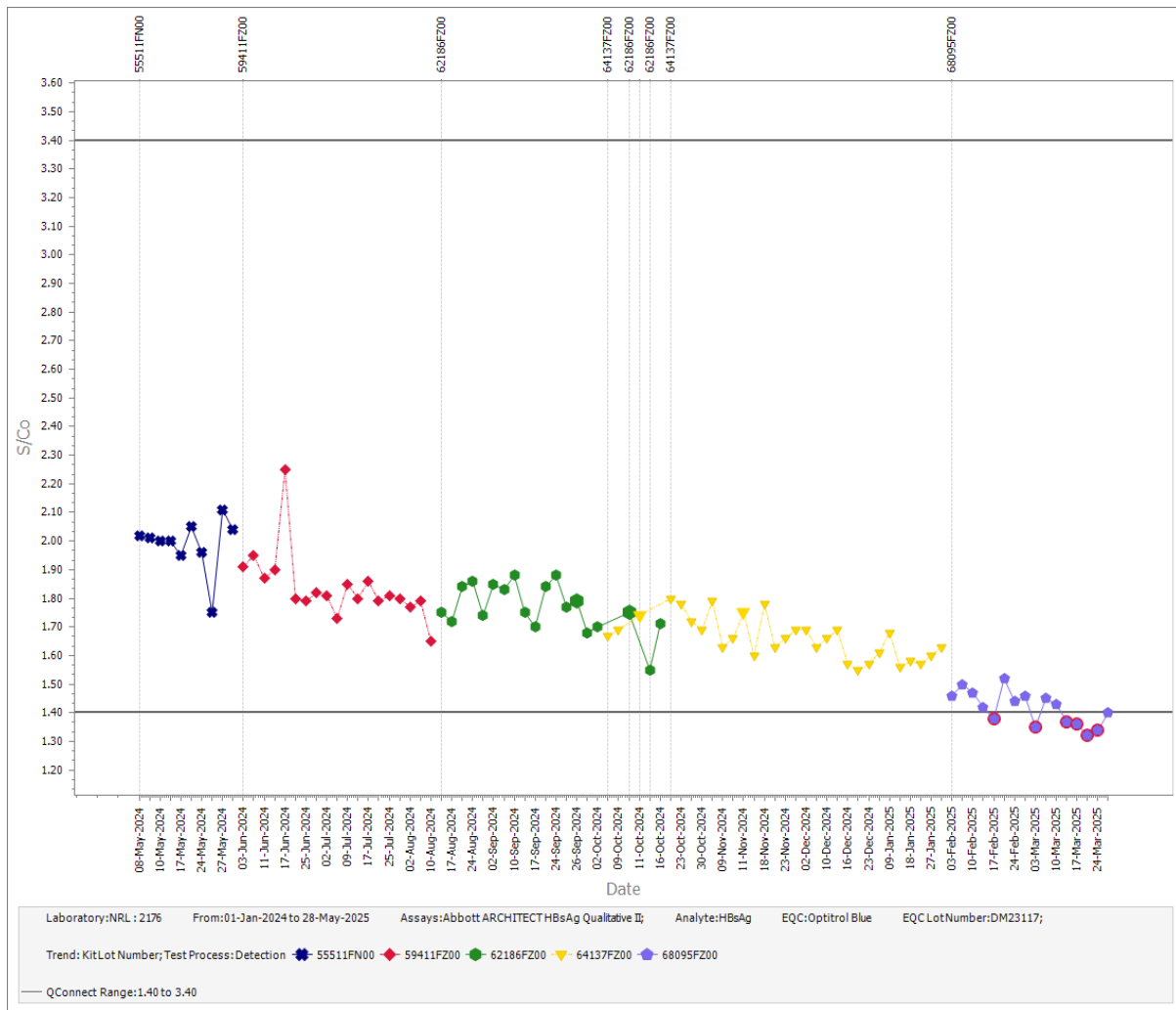


Figure 67- Participant 2176 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

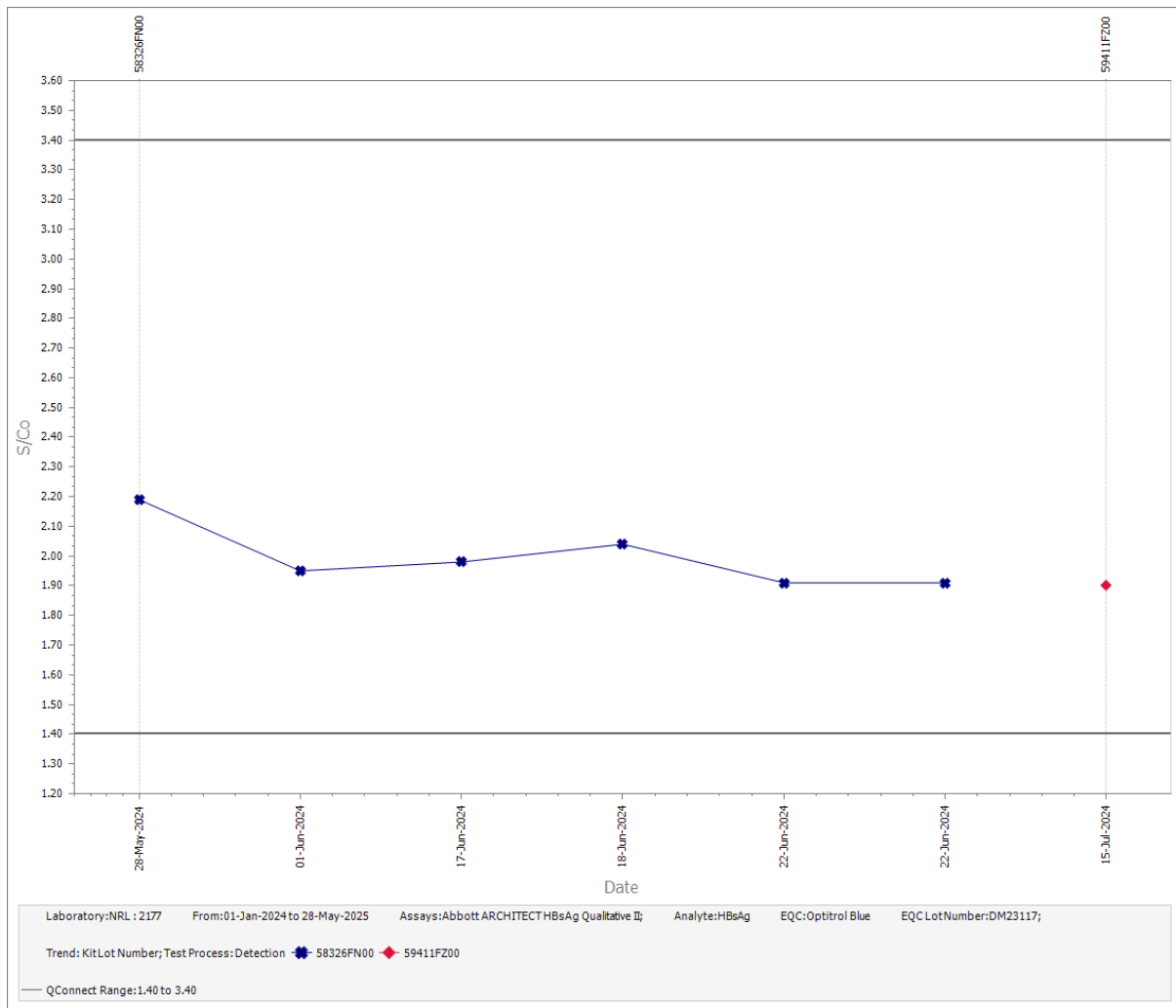


Figure 68- Participant 2177 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.

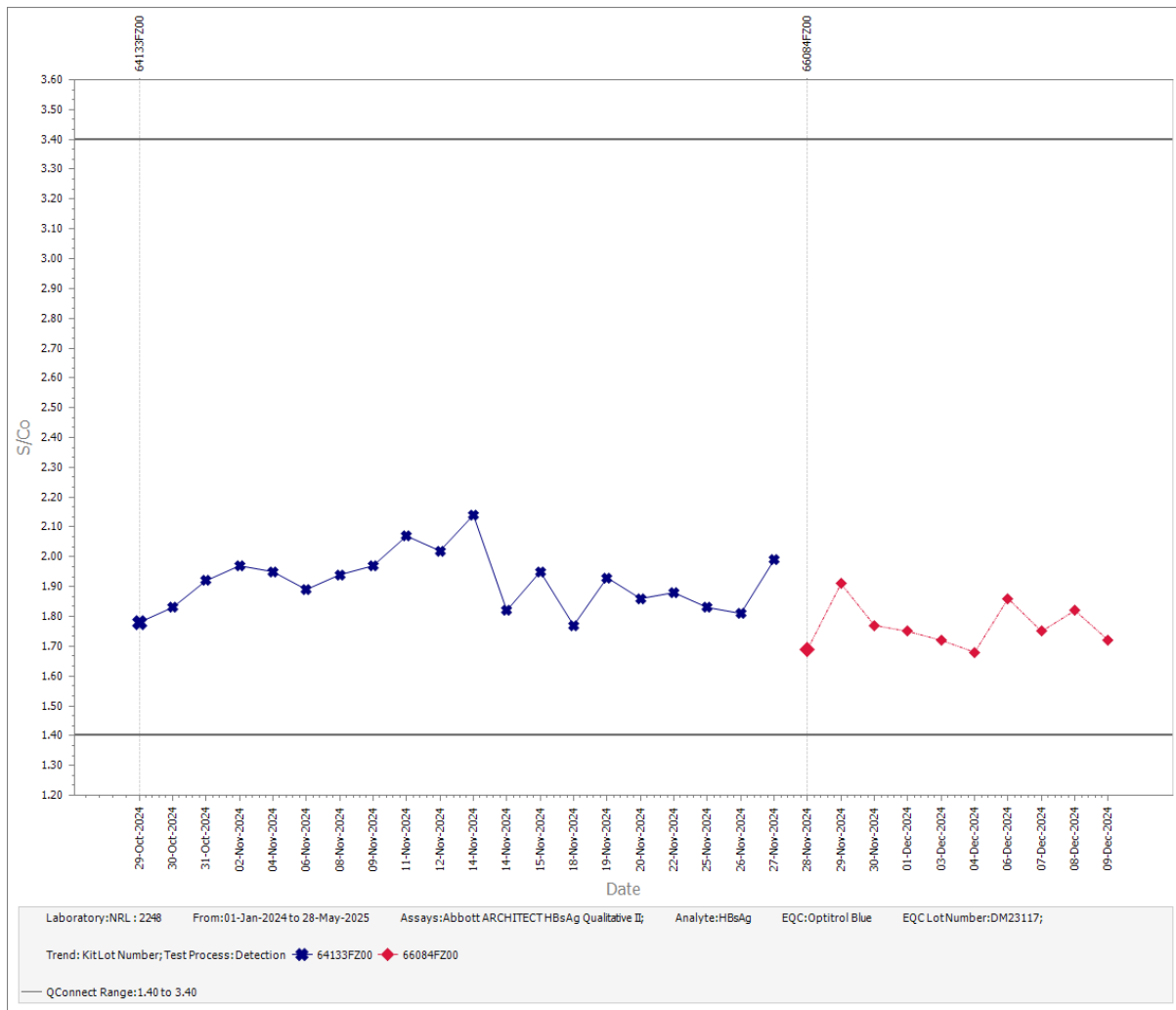
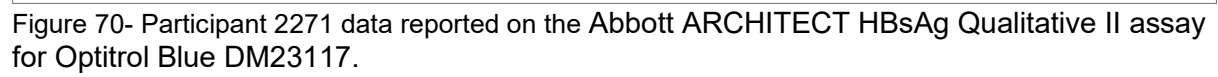


Figure 69- Participant 2248 data reported on the Abbott ARCHITECT HBsAg Qualitative II assay for Optitrol Blue DM23117.



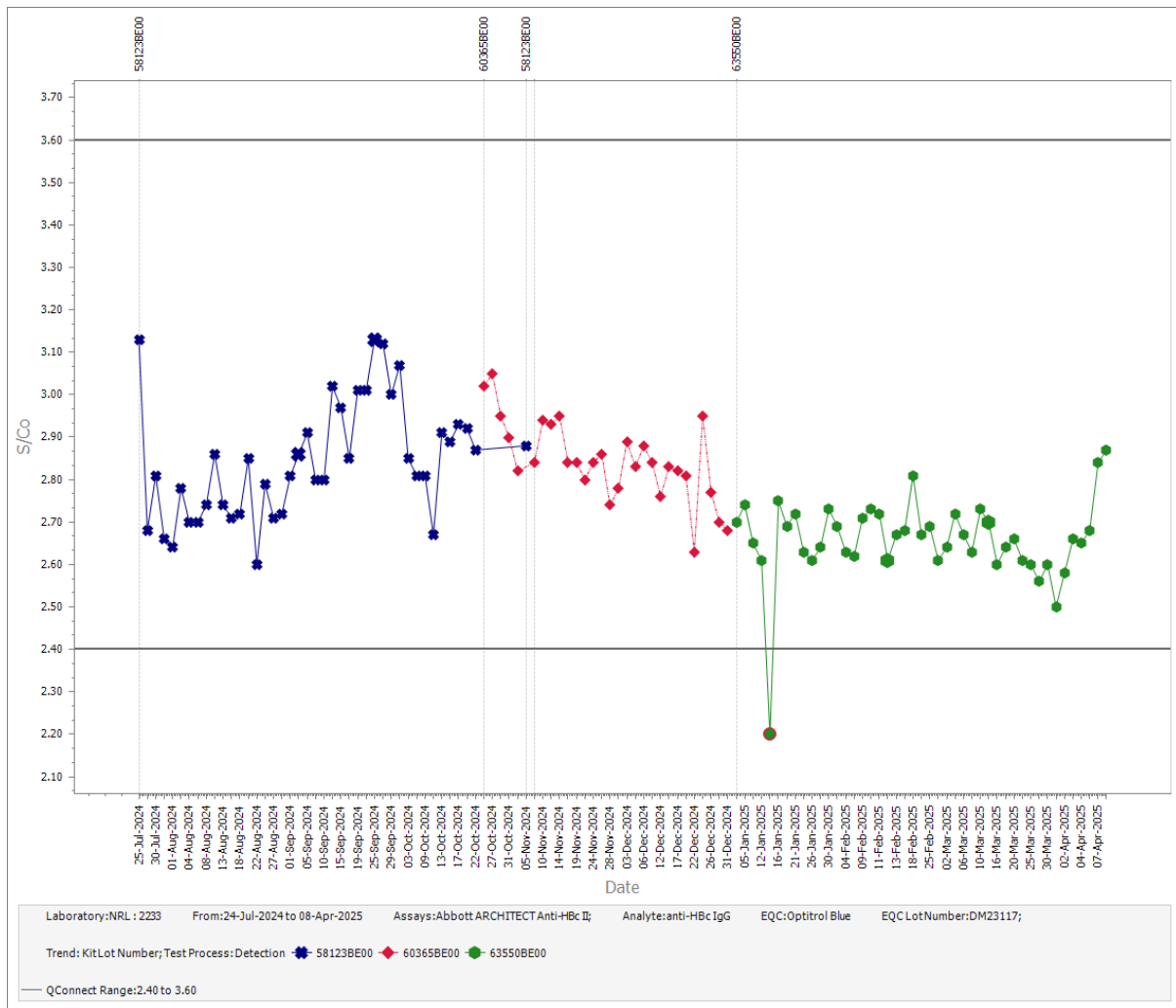




Figure 72- Participant 2233 data reported on the Abbott ARCHITECT Anti-HCV II assay for Optitrol Blue DM23117.

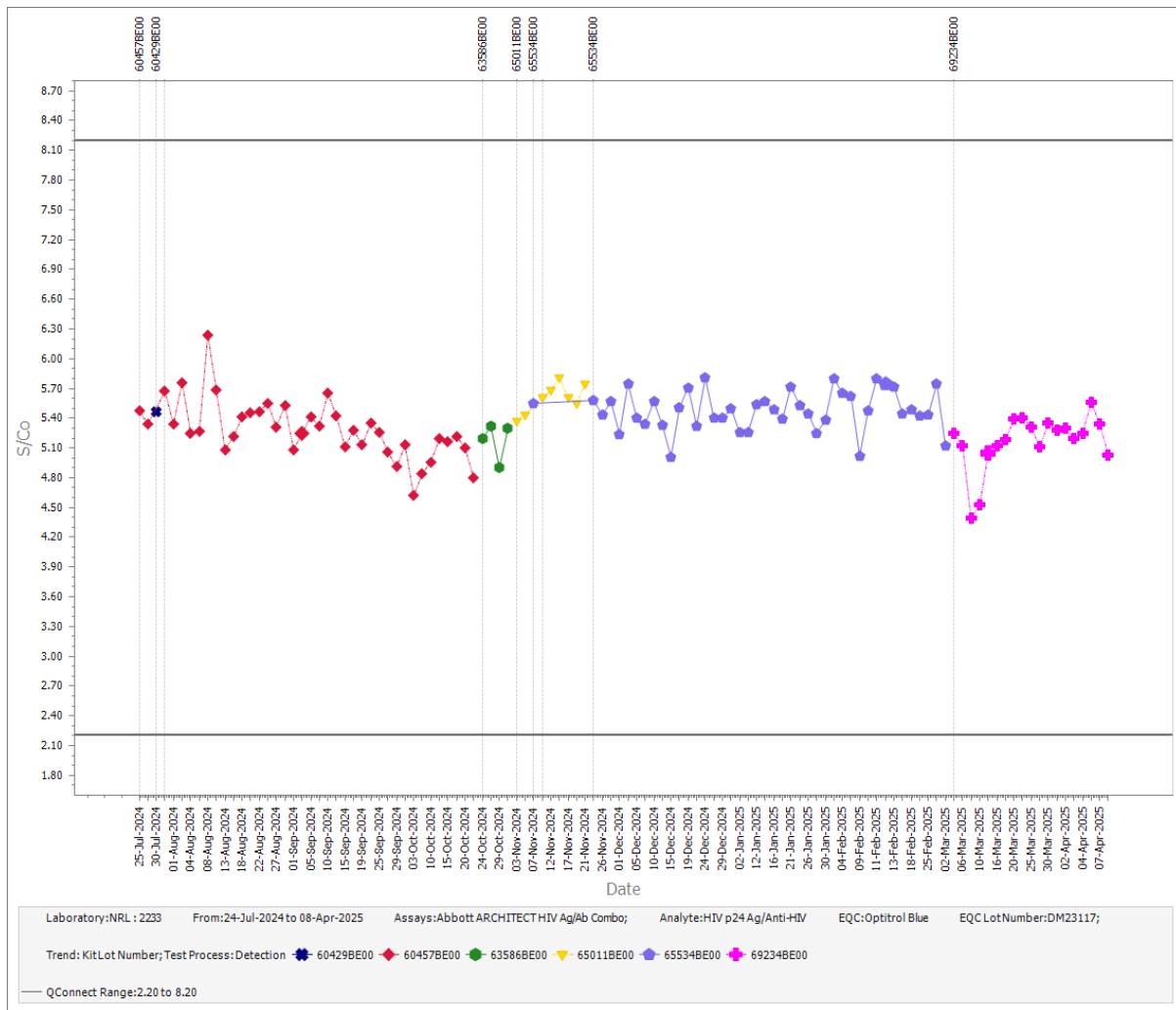


Figure 73-Participant 2233 data reported on the Abbott ARCHITECT HIV Ag/Ab Combo assay for Optitrol Blue DM23117.

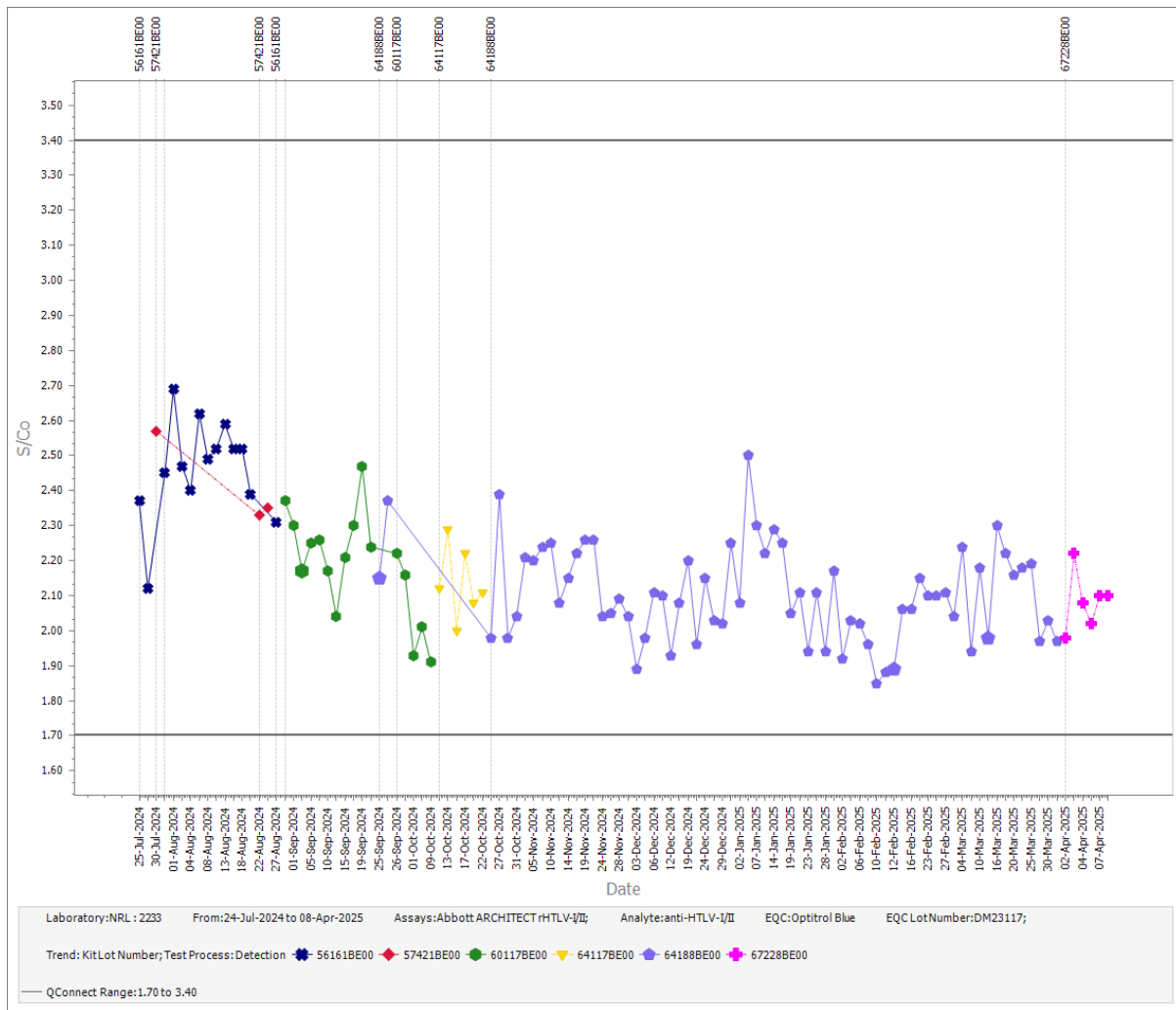


Figure 74- Participant 2233 data reported on the Abbott ARCHITECT rHTLV-I-II assay for Optitrol Blue DM23117.

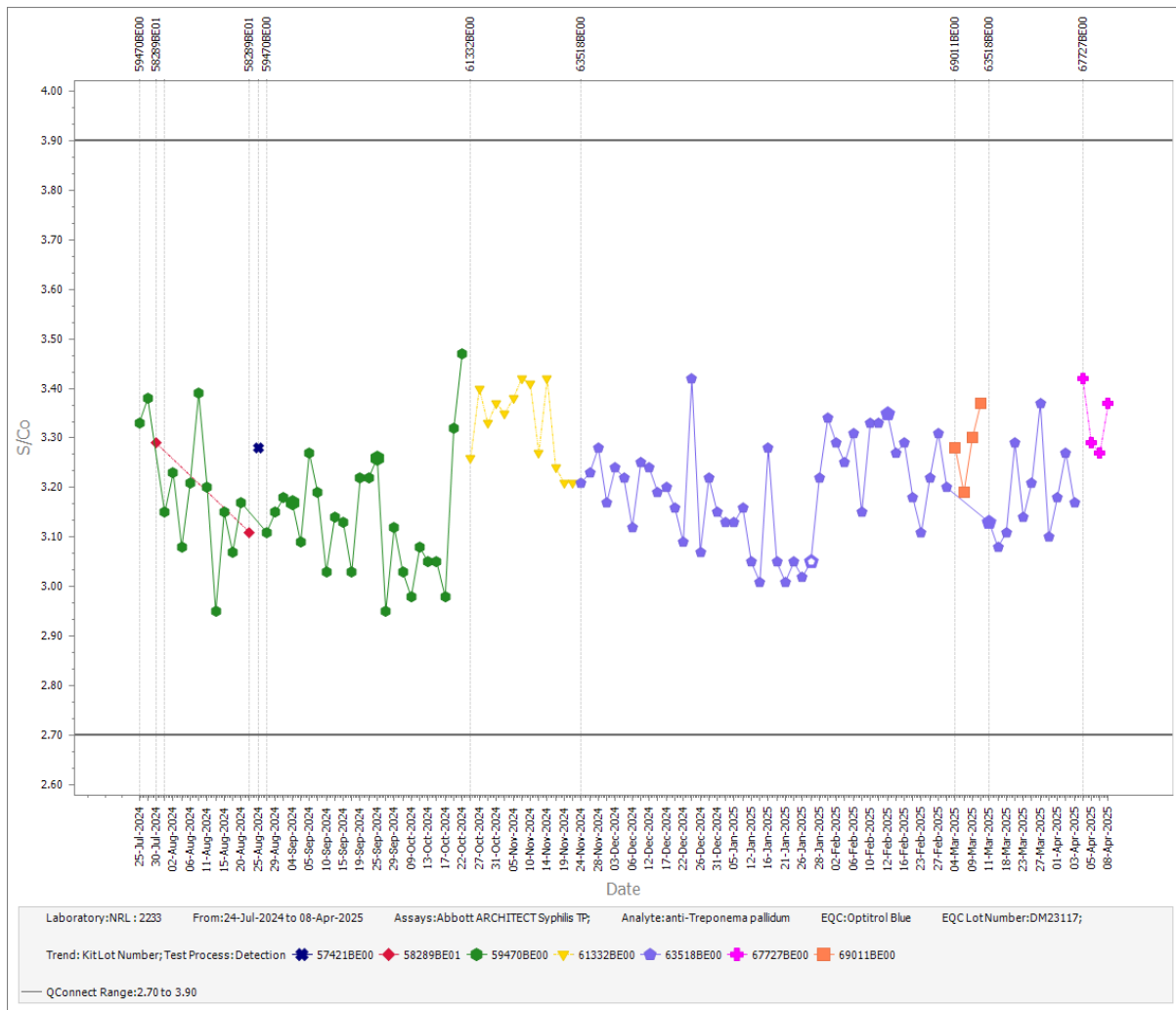


Figure 75- Participant 2233 data reported on the Abbott ARCHITECT Syphilis TP assay for Optitrol Blue DM23117.

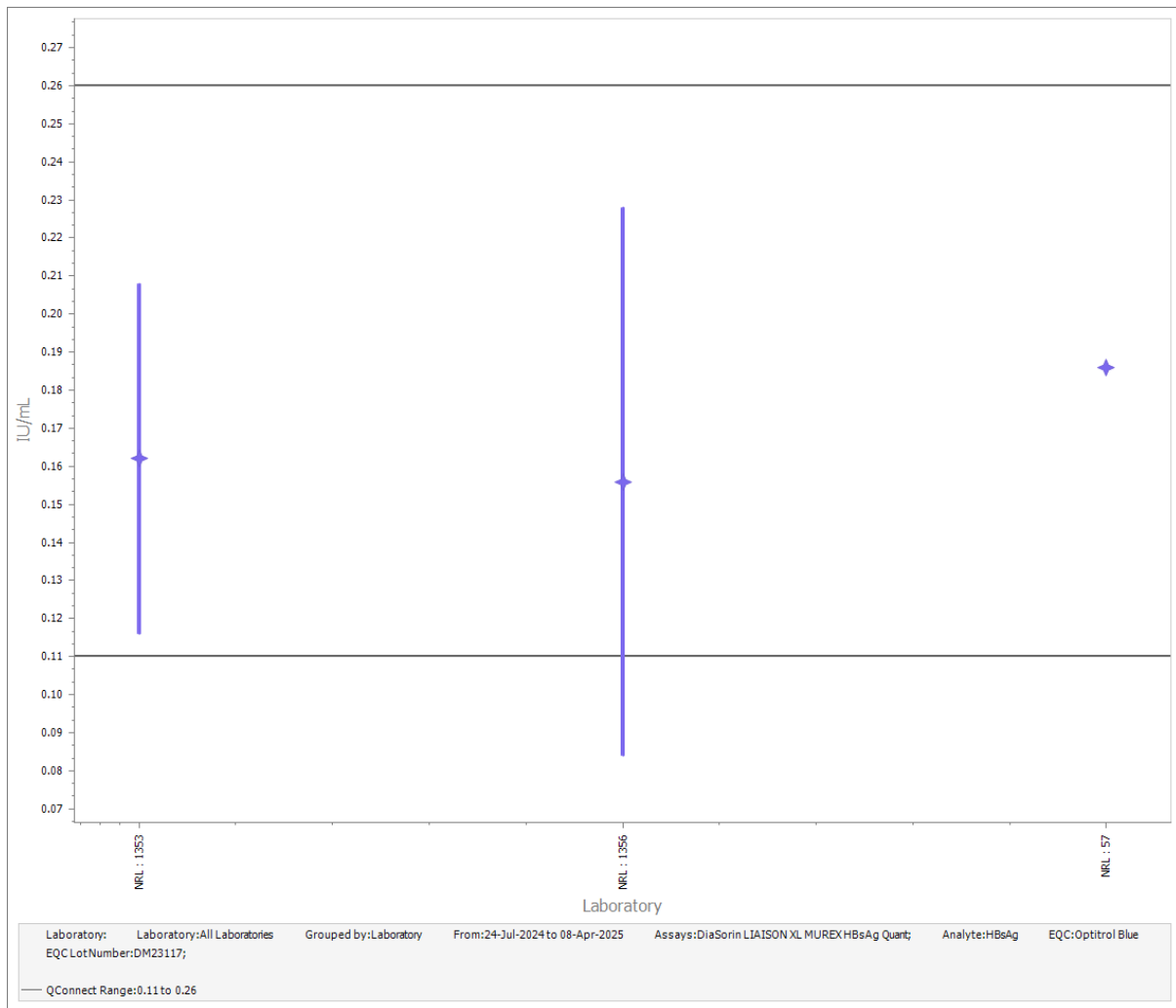


Figure 76-Peer group data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117 by participant.

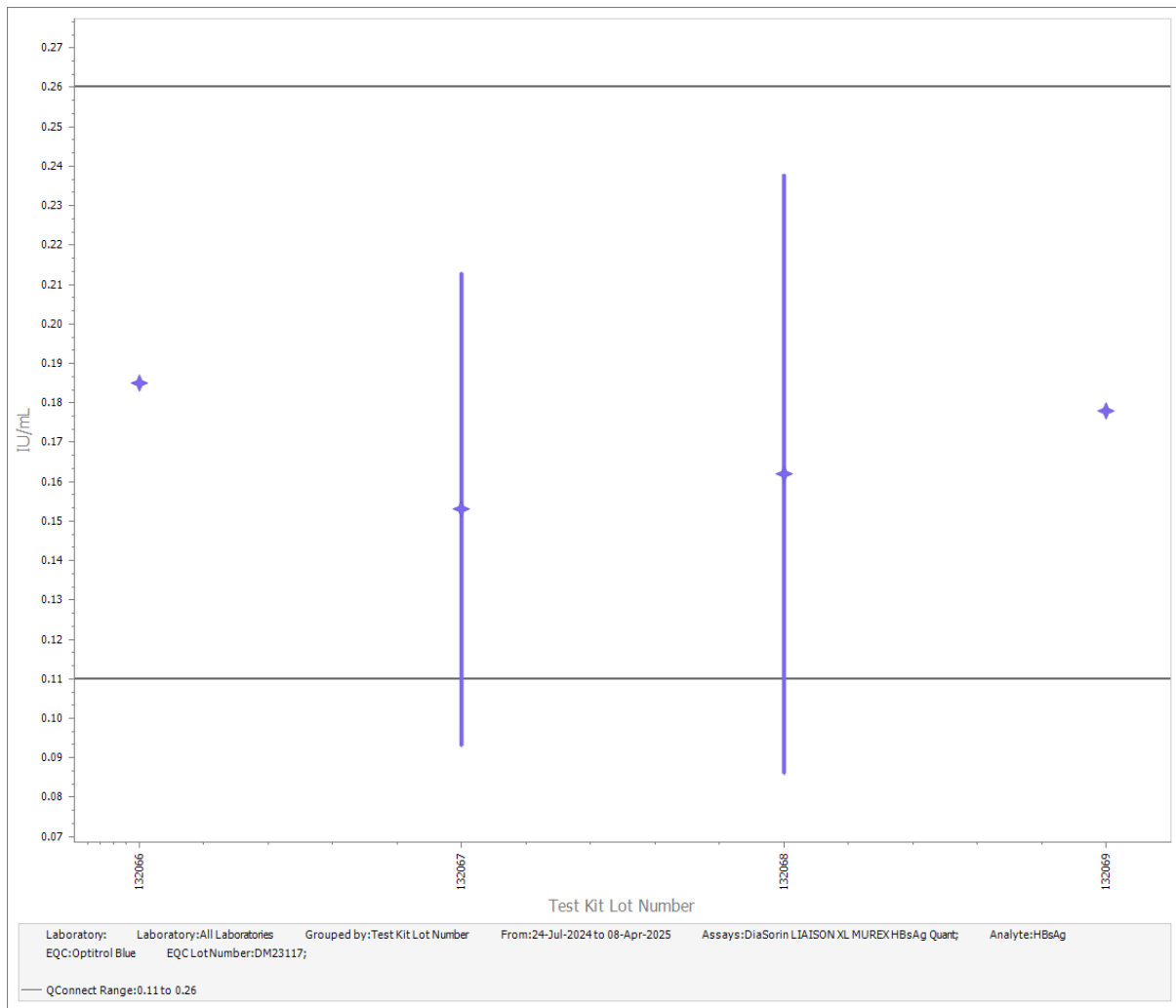


Figure 77- Peer group data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117 by reagent lot.

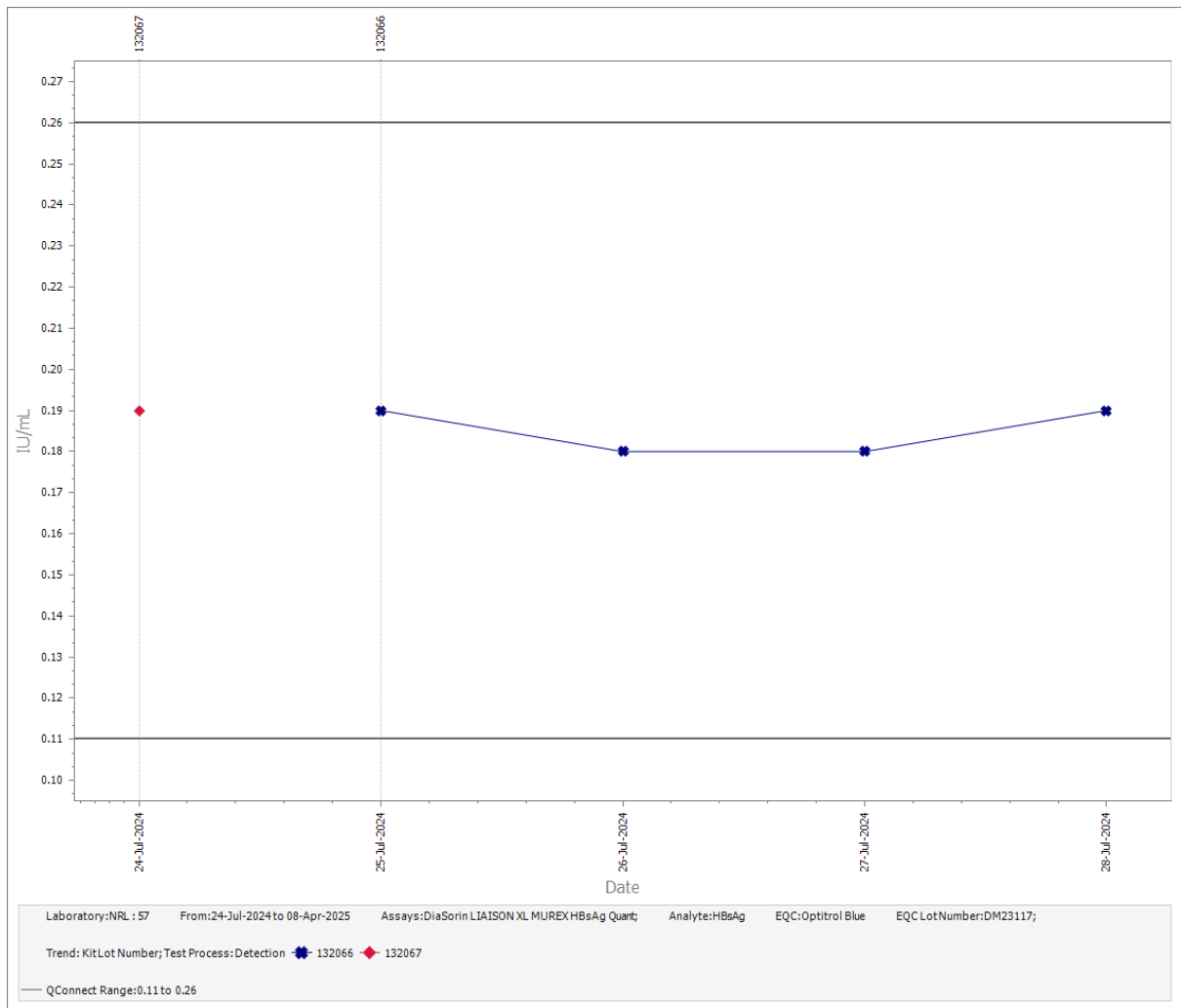


Figure 78-Partitipant 57 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.

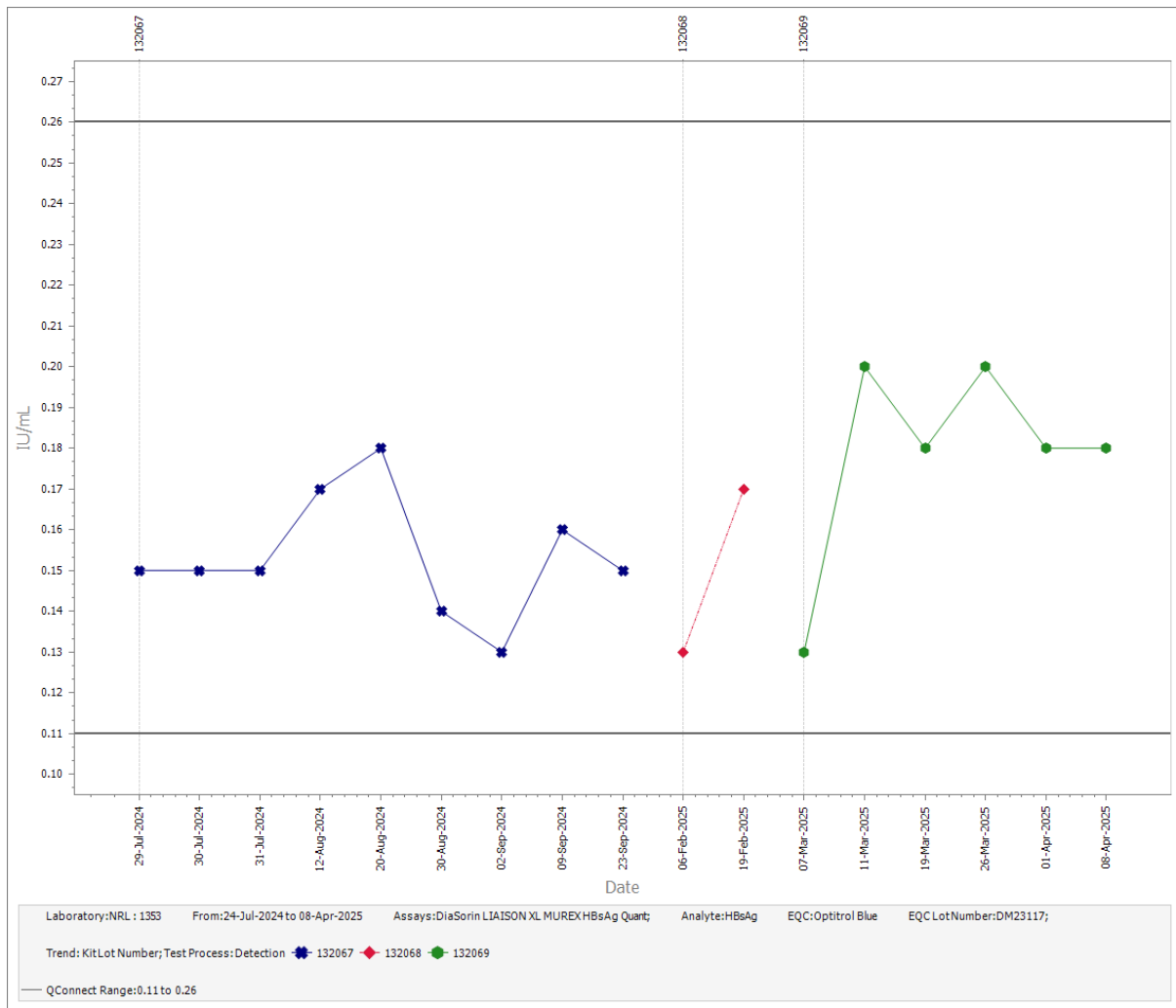


Figure 79-Participant 1353 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.

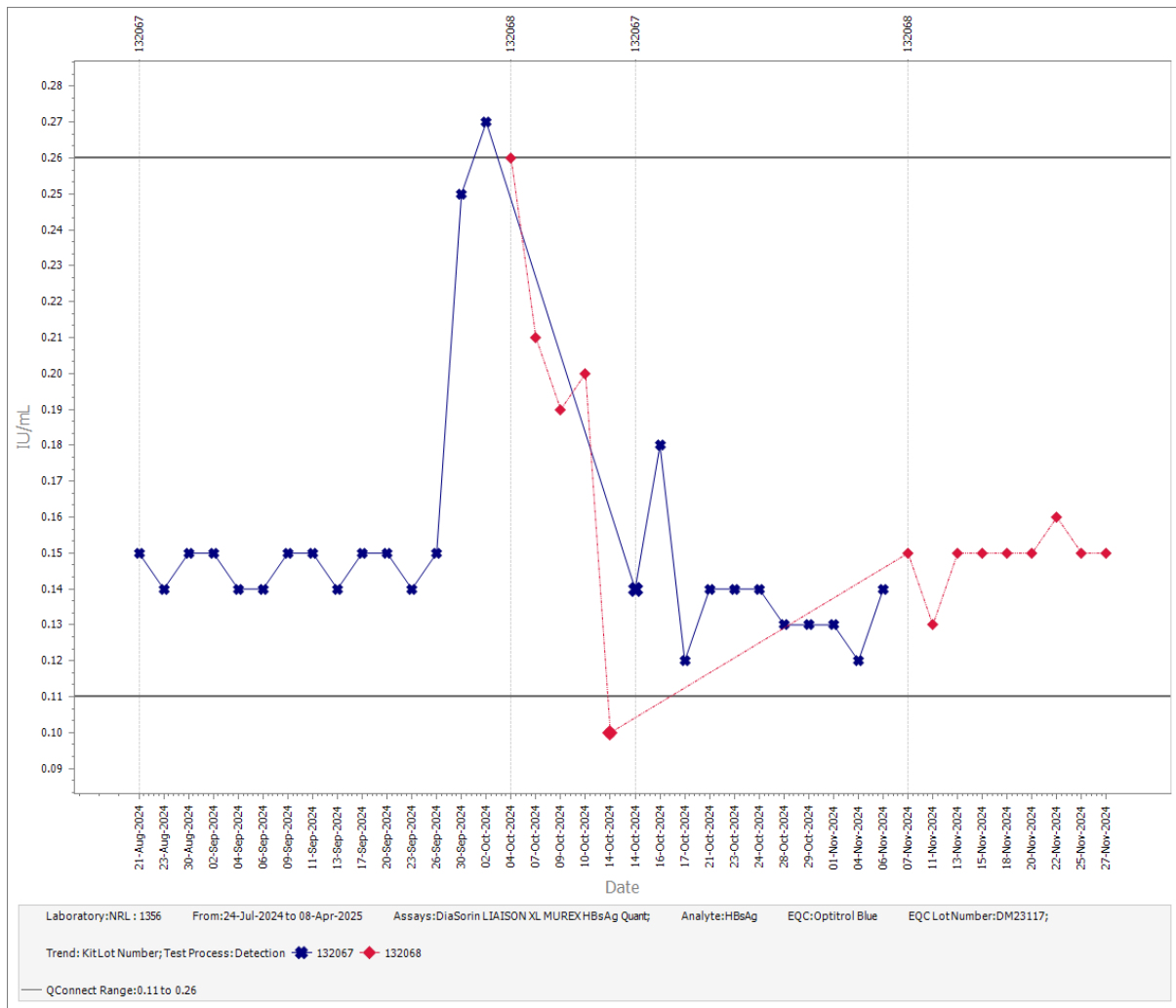


Figure 80-Participant 1356 data reported on the DiaSorin LIAISON XL MUREX HBsAg Quant assay for Optitrol Blue DM23117.

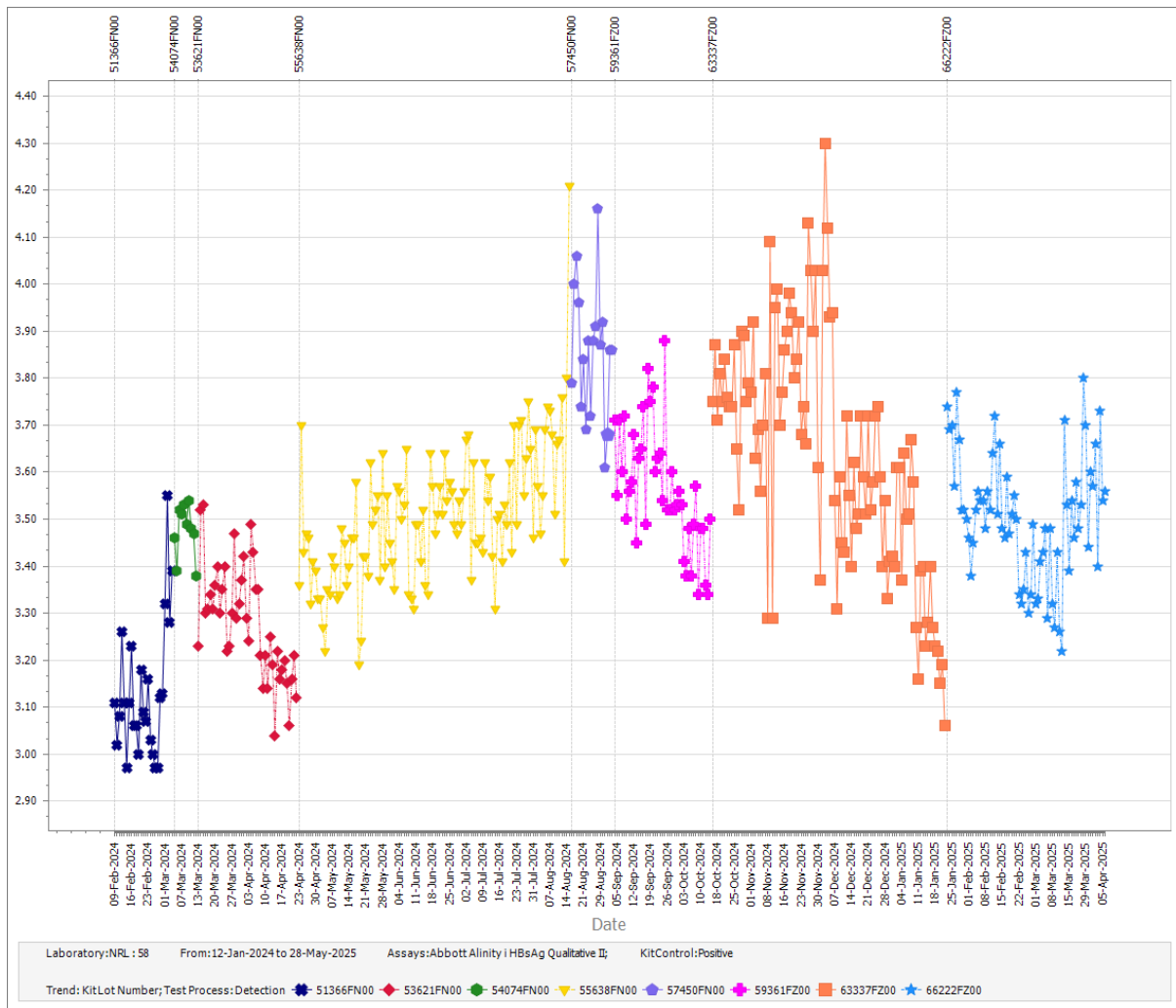


Figure 81-Abbott Positive Kit control data reported by Participant 58 on the Abbott Alinity i HBsAg Qualitative II assay.

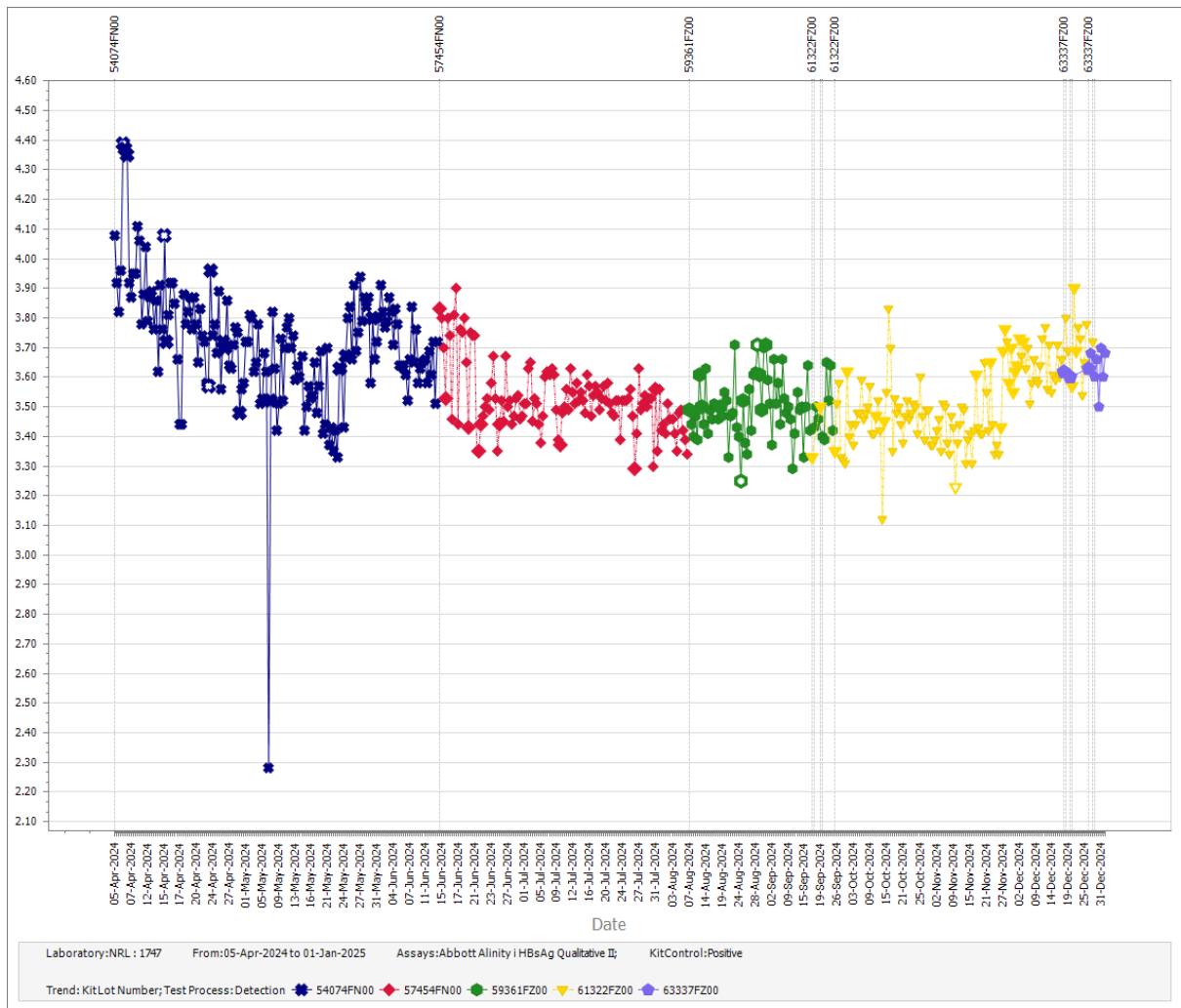


Figure 82 Abbott Positive Kit control data reported by Participant 1747 on the Abbott Alinity i HBsAg Qualitative II assay.

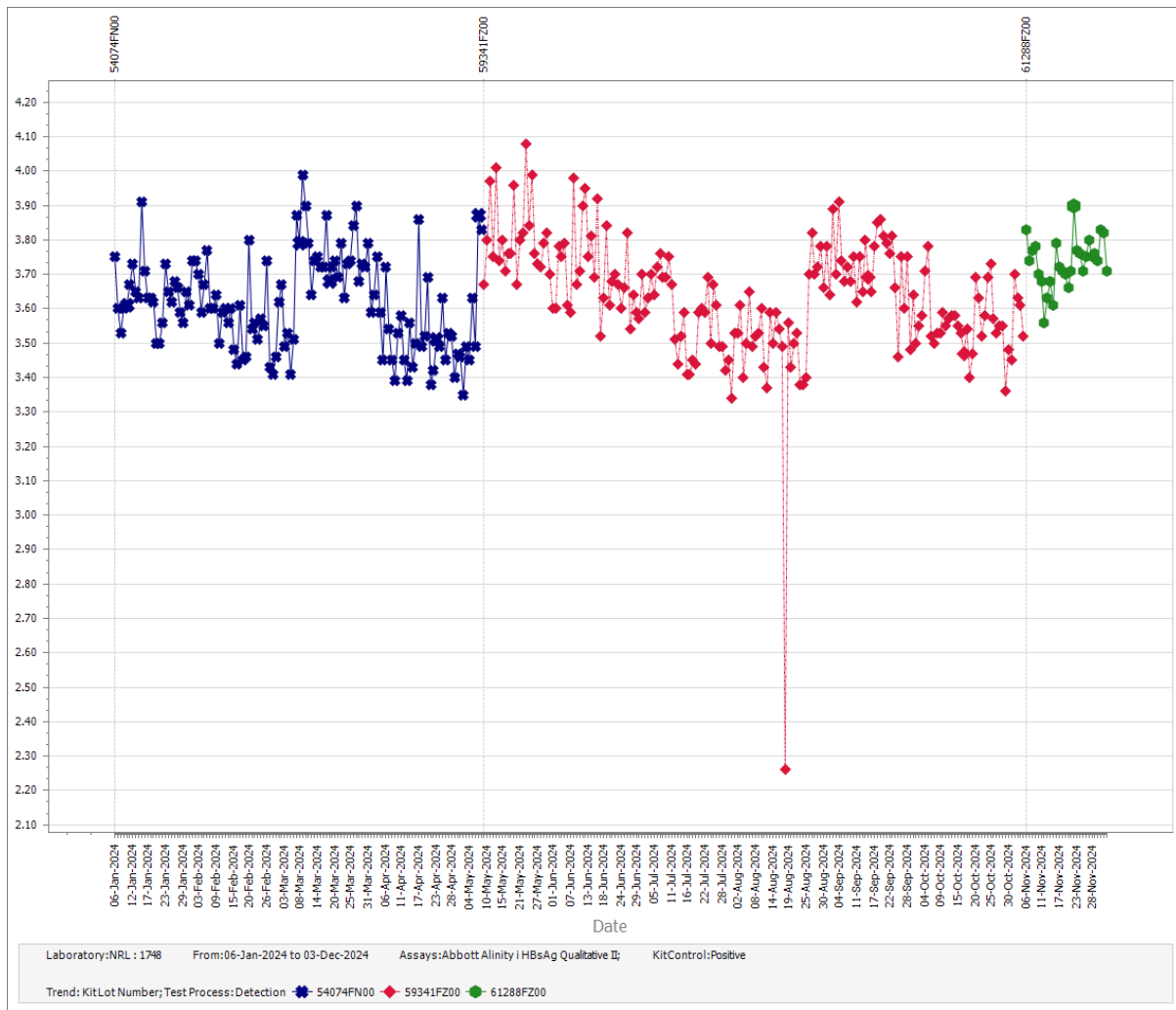


Figure 83- Abbott Positive Kit control data reported by Participant 1748 on the Abbott Alinity i HBsAg Qualitative II assay.

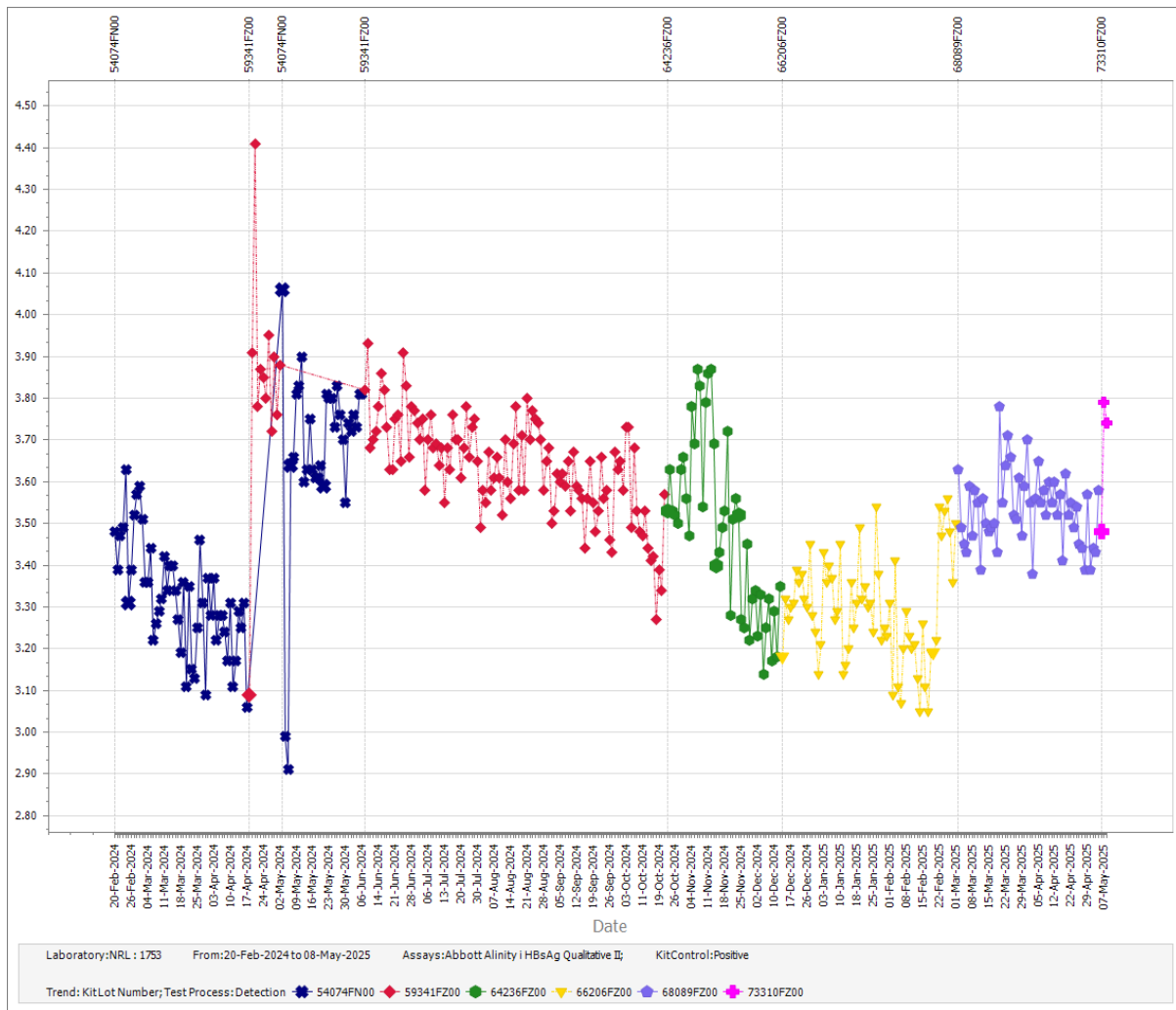


Figure 84- Abbott Positive Kit control data reported by Participant 1753 on the Abbott Alinity i HBsAg Qualitative II assay.

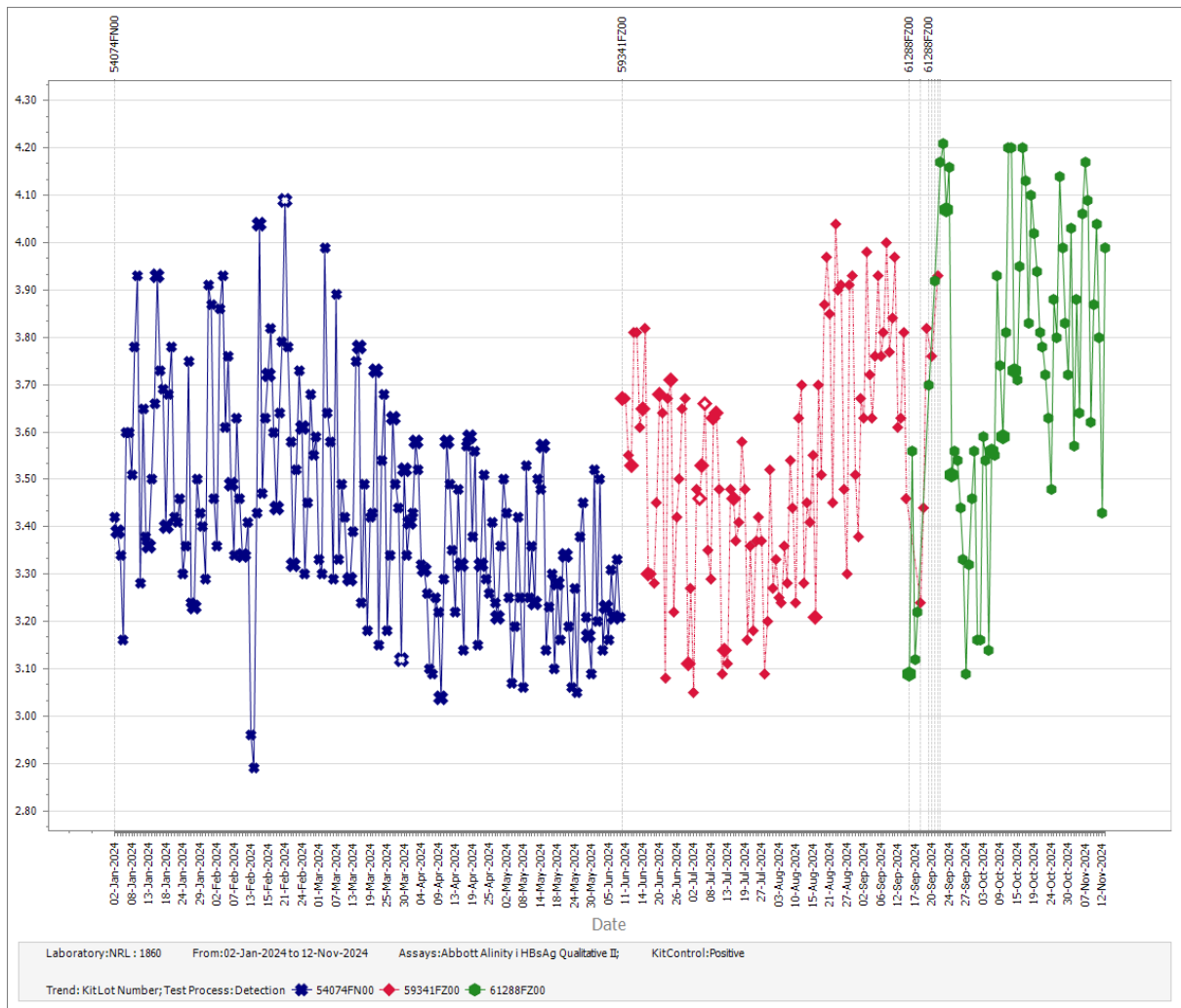


Figure 85- Abbott Positive Kit control data reported by Participant 1860 on the Abbott Alinity i HBsAg Qualitative II assay.

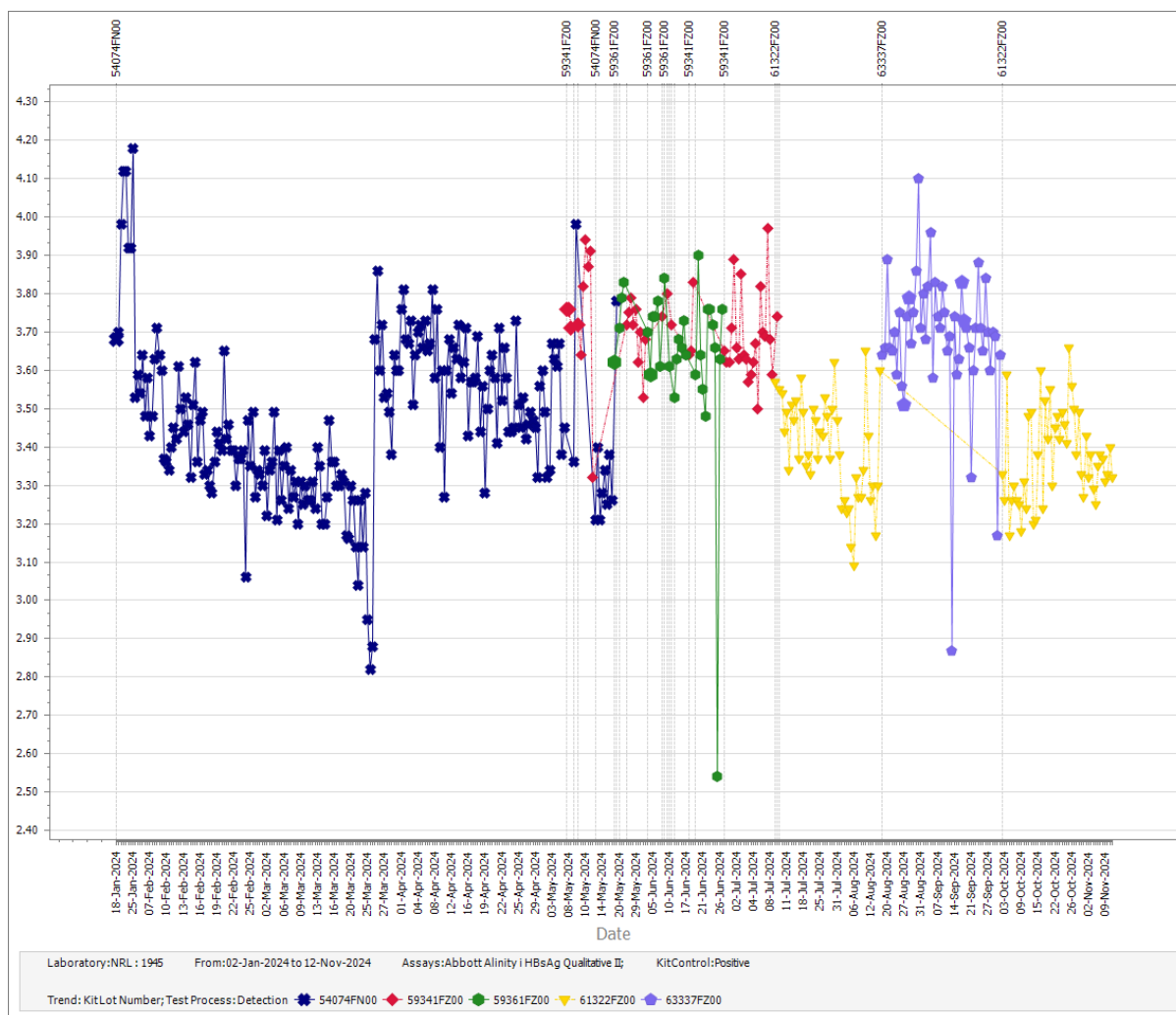


Figure 86- Abbott Positive Kit control data reported by Participant 1945 on the Abbott Alinity i HBsAg Qualitative II assay.

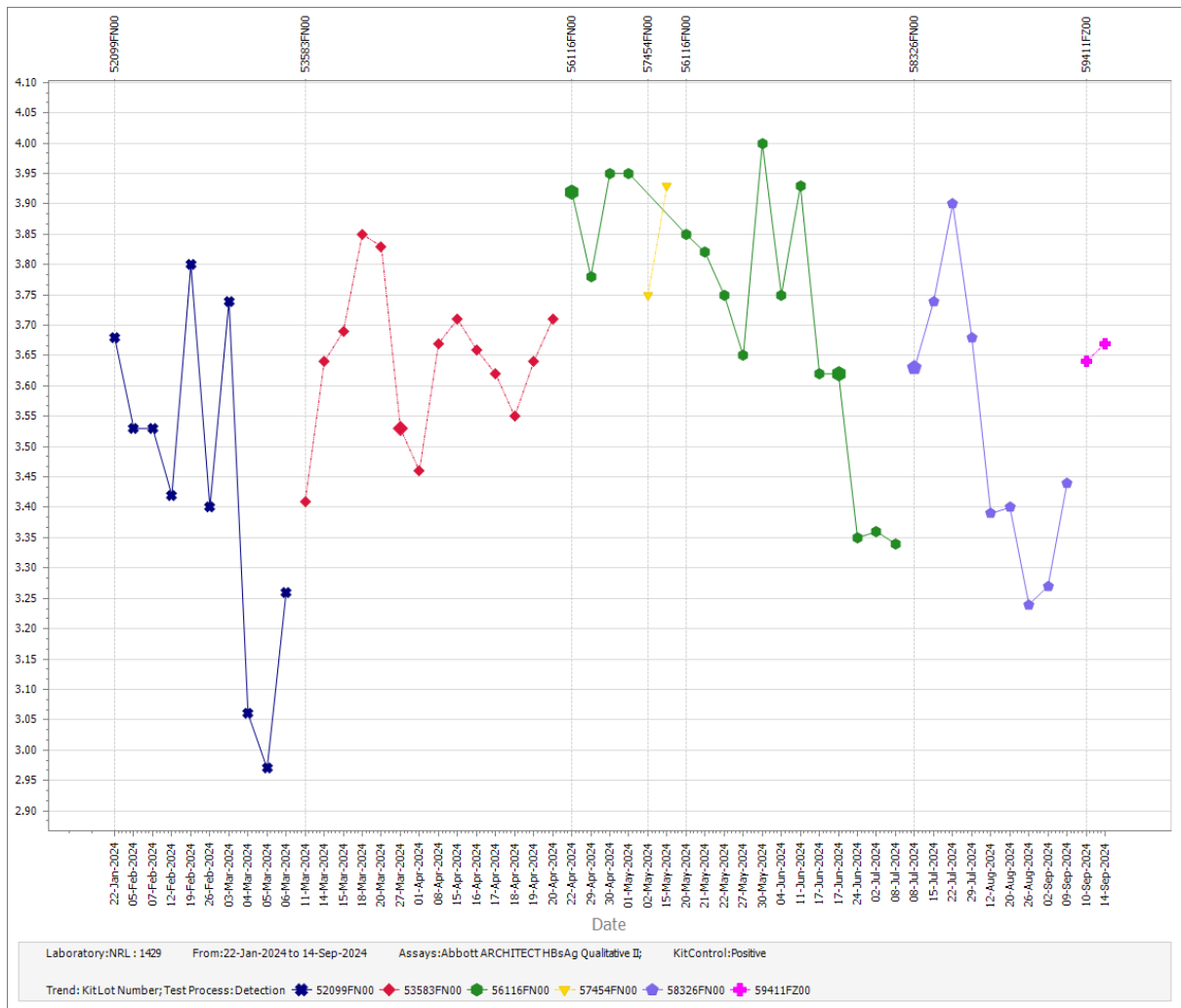


Figure 87- Abbott Positive Kit control data reported by Participant 1429 on the Abbott ARCHITECT HBsAg Qualitative II assay.

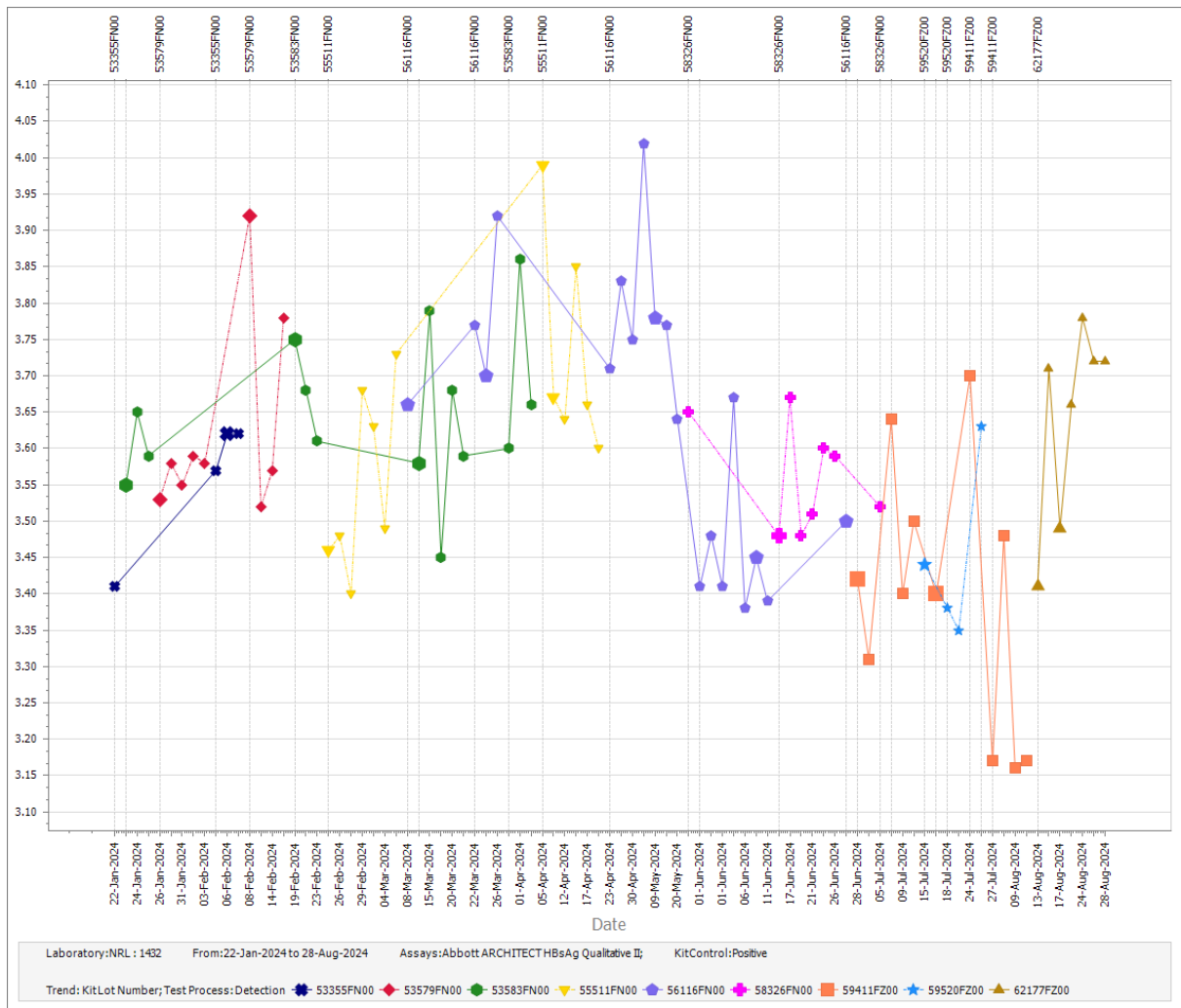


Figure 88- Abbott Positive Kit control data reported by Participant 1432 on the Abbott ARCHITECT HBsAg Qualitative II assay.

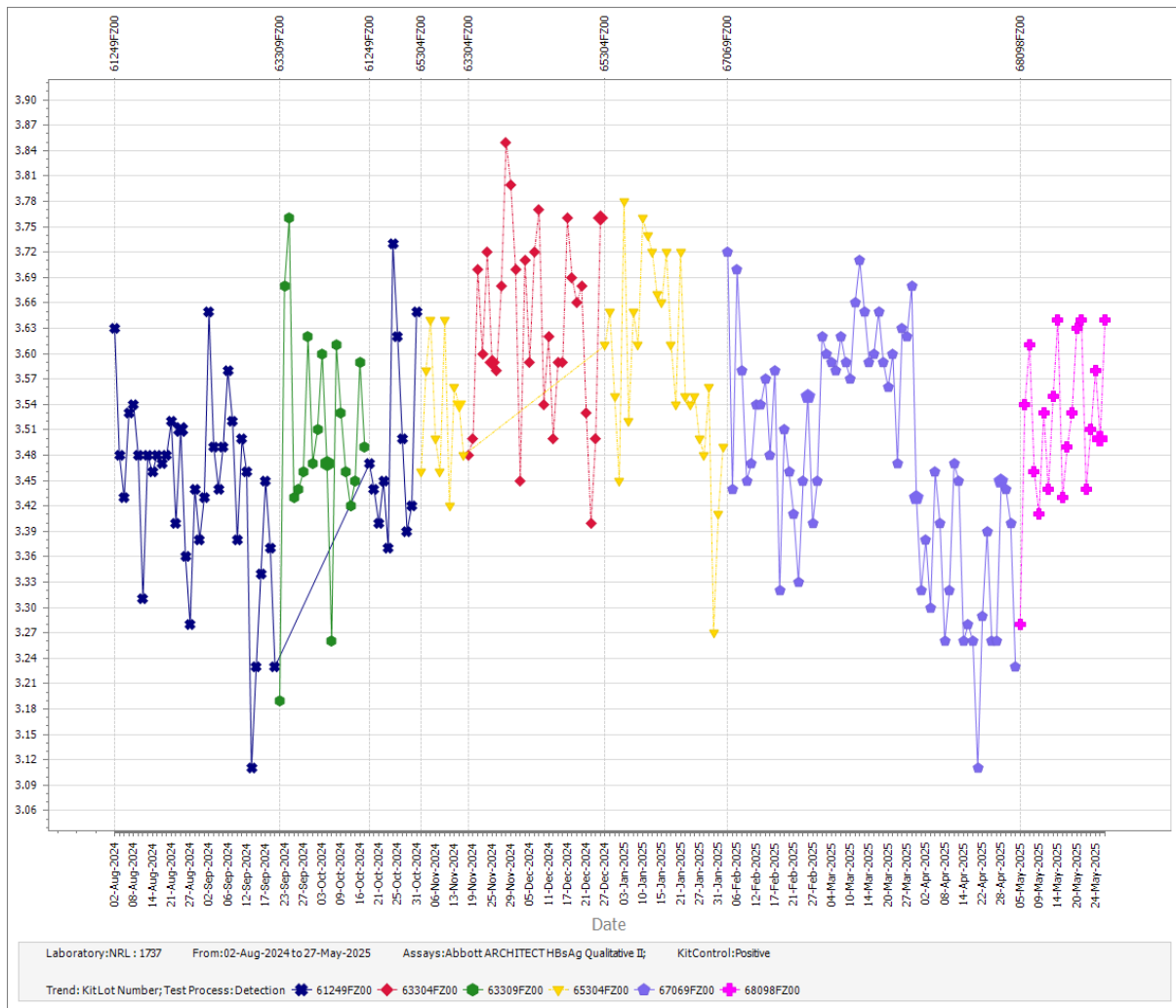


Figure 89- Abbott Positive Kit control data reported by Participant 1737 on the Abbott ARCHITECT HBsAg Qualitative II assay.

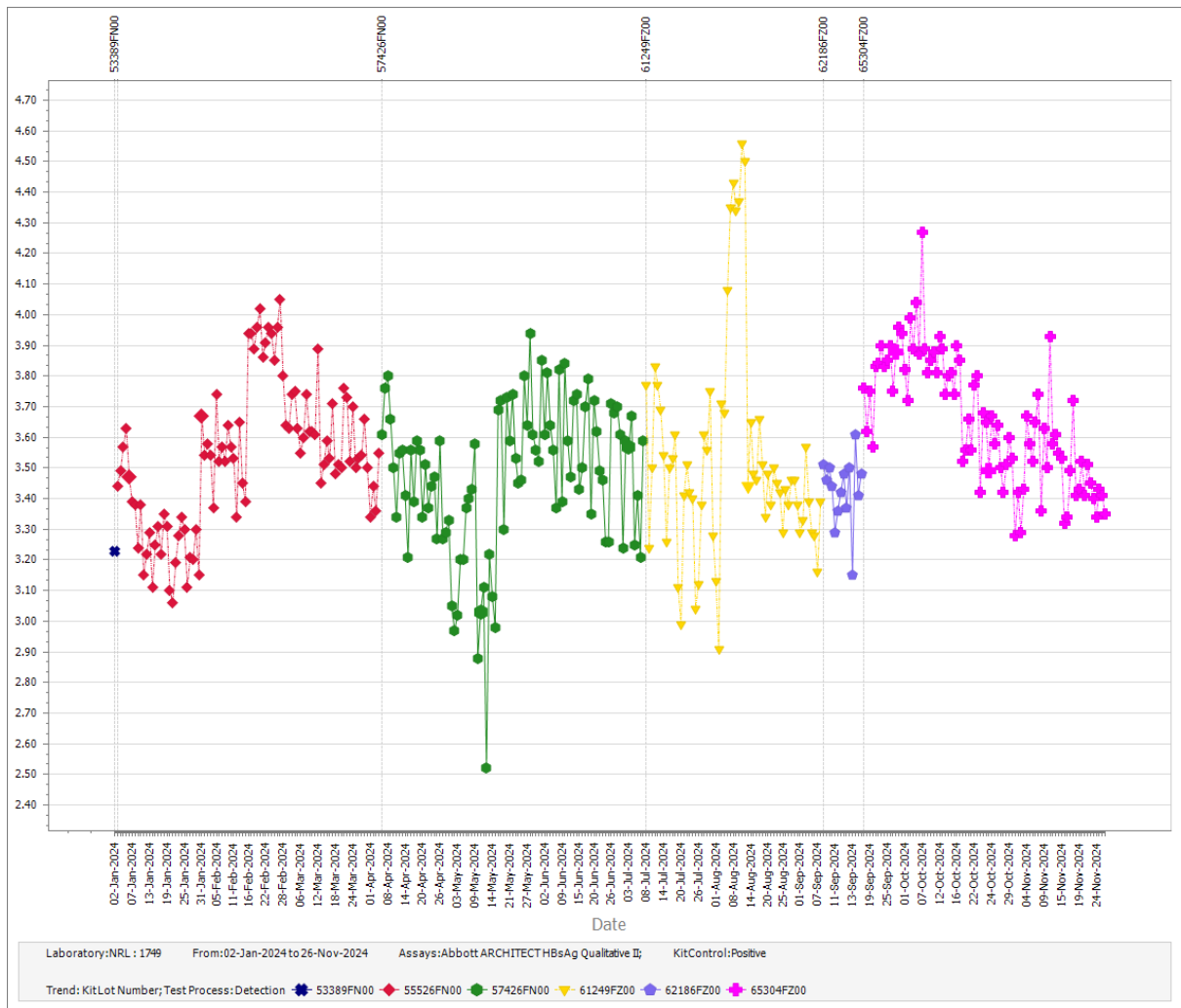


Figure 90- Abbott Positive Kit control data reported by Participant 1749 on the Abbott ARCHITECT HBsAg Qualitative II assay.

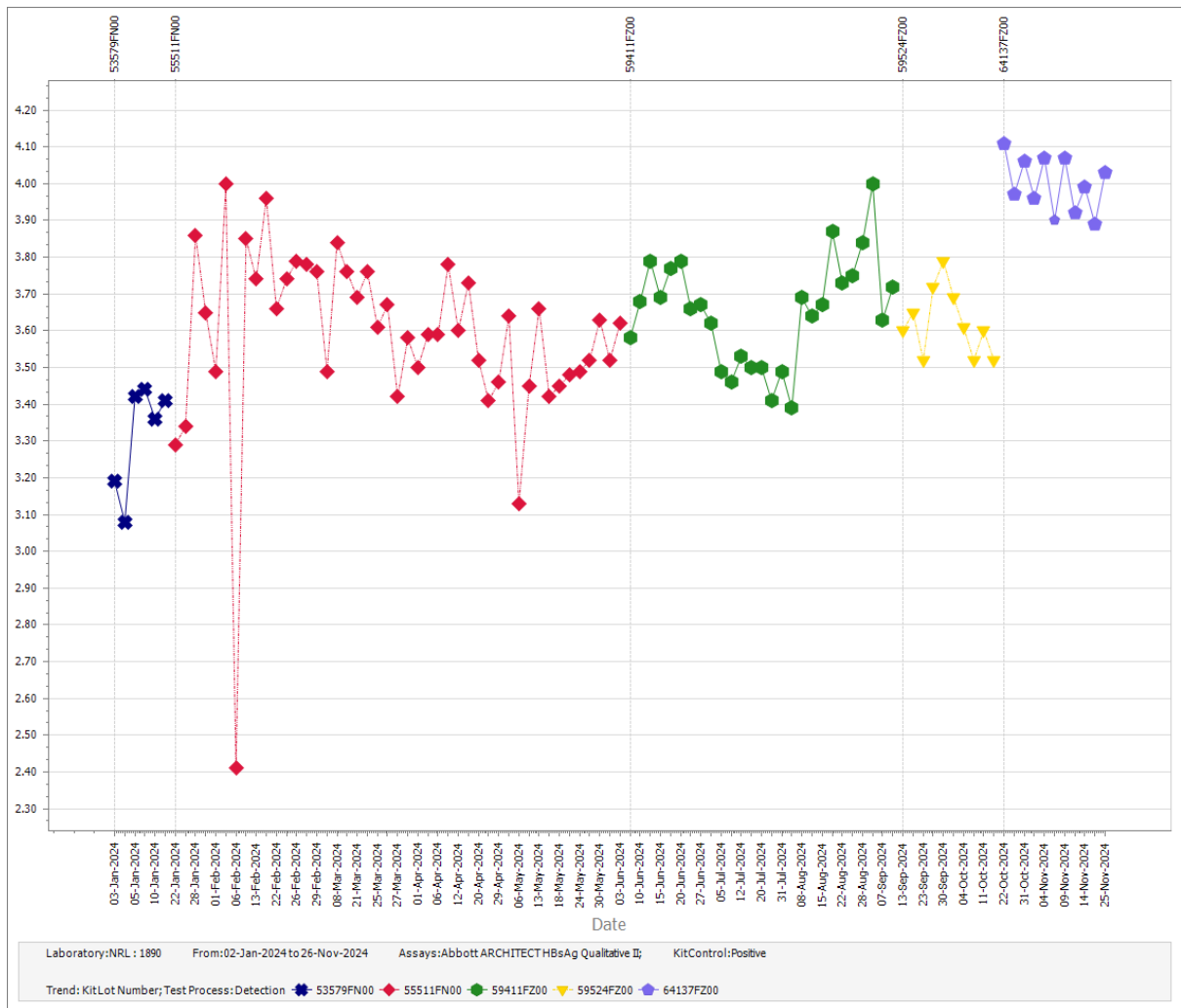


Figure 91- Abbott Positive Kit control data reported by Participant 1890 on the Abbott ARCHITECT HBsAg Qualitative II assay.