

QC Services Investigation: PMM-QC-2591

Contents

INTRODUCTION	3
FINDINGS	3
DISCUSSION.....	4
RECOMMENDATIONS.....	5
APPENDIX	6

Report prepared by Marina Karakaltsas
Authorised By: Kylie Davies / Joe Vincini
and distributed in the week beginning 2026/JUL/06

INTRODUCTION

NRL was contacted by Participant 451 with an observation of reactive results reported for Optitrol SeroNeg DM24140 when tested with the Abbott Alinity i HBsAg Qualitative II assay. NRL reviewed all data submitted to EDCNet by participants testing with Optitrol SeroNeg DM24140 on the Abbott Alinity i HBsAg Qualitative II assay to establish if these unexpected results were observed for any other participants or if it was isolated to Participant 451.

FINDINGS

- Figure 1 - Peer group data for Optitrol SeroNeg lots DM21045, DM22214 and DM24140 data, reported on the Abbott Alinity i HBsAg Qualitative assay, by participant.
- Figure 2 - Peer group data for Optitrol SeroNeg DM24140 data, reported on the Abbott Alinity i HBsAg Qualitative assay, by participant.
- Figure 3 - Participant 451 data reported for Optitrol SeroNeg DM21045 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.
- Figure 4 - Participant 451 data reported for Optitrol SeroNeg DM22214 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.
- Figure 5 - Participant 451 data reported for Optitrol SeroNeg DM24140 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.
- Figure 6 - Participant 451 data reported for Optitrol SeroNeg lots DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.
- Figure 7 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HBc IgM assay.
- Figure 8 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i Anti-HBc II.
- Figure 9 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i Anti-HBe assay.
- Figure 10 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 tested on the Abbott Alinity i Anti-HBs assay.
- Figure 11 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HCV II assay.
- Figure 12 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HAV Ab - IgG assay.
- Figure 13 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HAV Ab – IgM assay.
- Figure 14 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HIV Ag/Ab Combo assay.
- Figure 15 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i rHTLV-I/II assay.
- Figure 16 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i Syphilis TP assay.
- Figure 17 - Participant 451 data reported for Optitrol Blue DM23204 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.
- Figure 18 - Participant 451 data reported for the Abbott Negative kit control when testing in the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 19 - Participant 1620 data reported for Optitrol SeroNeg DM24140 when testing in the Abbott Alinity i HBsAg Qualitative II assay.
- Figure 20 - Participant 1748 data reported for Optitrol SeroNeg DM24140 when testing in the Abbott Alinity i HBsAg Qualitative II assay.

DISCUSSION

Three participants reported data for Optitrol SeroNeg lots (DM21045, DM22214 and DM24140) on the Abbott Alinity i HBsAg Qualitative assay. These three Optitrol SeroNeg lots were in use across 13 reagent lots for the period investigated (01 January 2024 through August 2025). Only Participant NRL 451 reported data with a positive S/Co value (Figure 1), all peer group data were reported as expected below the assay cut off (1.00 S/Co).

Two participants reported data for Optitrol SeroNeg DM24140 across five reagent lots on the Abbott Alinity i HBsAg Qualitative assay. Only Participant NRL 451 reported data with a positive S/Co value (Figure 2).

Figures 3 through 6 illustrate data reported for Participant 451 for Optitrol SeroNeg lots DM21045, DM22214, DM24140 individually and combined, respectively. No unexpected positive data were observed for Optitrol SeroNeg DM21045. Four positive data were reported for Optitrol SeroNeg DM22214 across three of four reagent lots in use and 11 positive data were reported for Optitrol SeroNeg DM24140 across two of three reagent lots in use. Figure 5 also illustrates a higher incidence of both high negative S/Co values and number of unexpected positive results reported for SeroNeg DM24140 for data reported from late May 2025 by Participant 451.

Figures 7 to 16 show data for Participant 451 across all other Alinity i assays where Optitrol SeroNeg lots DM21045, DM22214 and DM24140 were in use. Very few unexpected positive results were observed. Of these, Figure 10 shows one reactive result from 906 results tested reported for the Abbott Alinity i Anti-HBc assay, which was invalidated by the participant and found non-reactive on repeat testing. Figure 12 shows four of 874 unexpected reactive results reported for Optitrol SeroNeg when tested on the Abbott Alinity i HAV Ab-IgG assay. All unexpected reactive results were reported on one of seven reagent lots in use (lot 72396BE00). In all three cases the sample was repeated by the participant and reported with an expected negative S/Co value. Figure 15 shows one reactive result out of 205 results where the lab reported it as an error and upon repeat testing reported a negative result.

No unexpected data were reported by Participant 451 for either Optitrol Blue or the Abbott Negative Kit control samples (Figures 17 and 18)

Figures 19 and 20 show individual participant data for Participants 1620 and 1748 for Optitrol SeroNeg DM24140 by reagent lot. No unexpected positive data were observed.

Participant 451 communicated to NRL that they had observed reactive results on initial testing of Optitrol SeroNeg DM24140 on the Abbott Alinity i HBsAg Qualitative assay and on repeat testing of the same sample; results were reported as negative.

Participant 451 also communicated to NRL that they had contacted Abbott Laboratories regarding the unexpected and inconsistent positive results reported for the Optitrol SeroNeg sample. In response Abbott Alinity i technicians inspected and preformed trouble shooting on probes, vortex, degasser and changed valves. Abbott suggested testing with another reagent lot. The pattern of unexpected results for Optitrol SeroNeg reactive on initial testing and negative on repeat continued to be observed.

Participant 451 confirmed to NRL that they were observing the same issue with patient samples, where data were initially weak positive but negative when retested.

Abbott Laboratories continue to investigate this issue with Participant 451.

RECOMMENDATIONS

NRL recommends participant continuing working with Abbott laboratories until a root cause can be identified and resolved. Examples of likely root cause could include sample carryover, inadequate washing and/or damaged sample probes.

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

For further assistance with EDCNet data please contact NRL at qconnect@nrlquality.org.au

NRL will continue to monitor Optitrol SeroNeg results on the Abbott Alinity i HBsAg Qualitative II assay.

APPENDIX

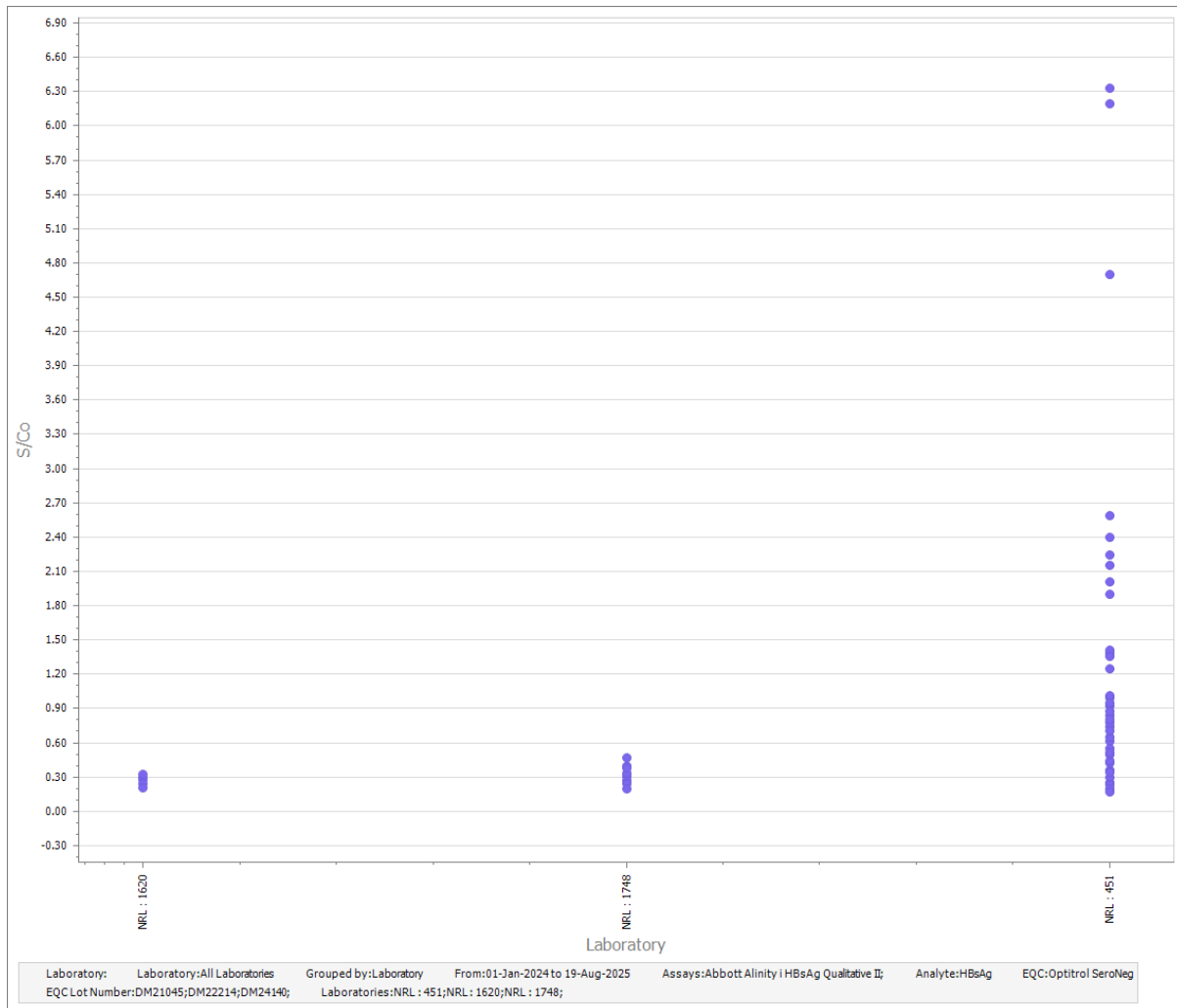


Figure 1 - Peer group data for Optitrol SeroNeg lots DM21045, DM22214 and DM24140 data, reported on the Abbott Alinity i HBsAg Qualitative assay, by participant.

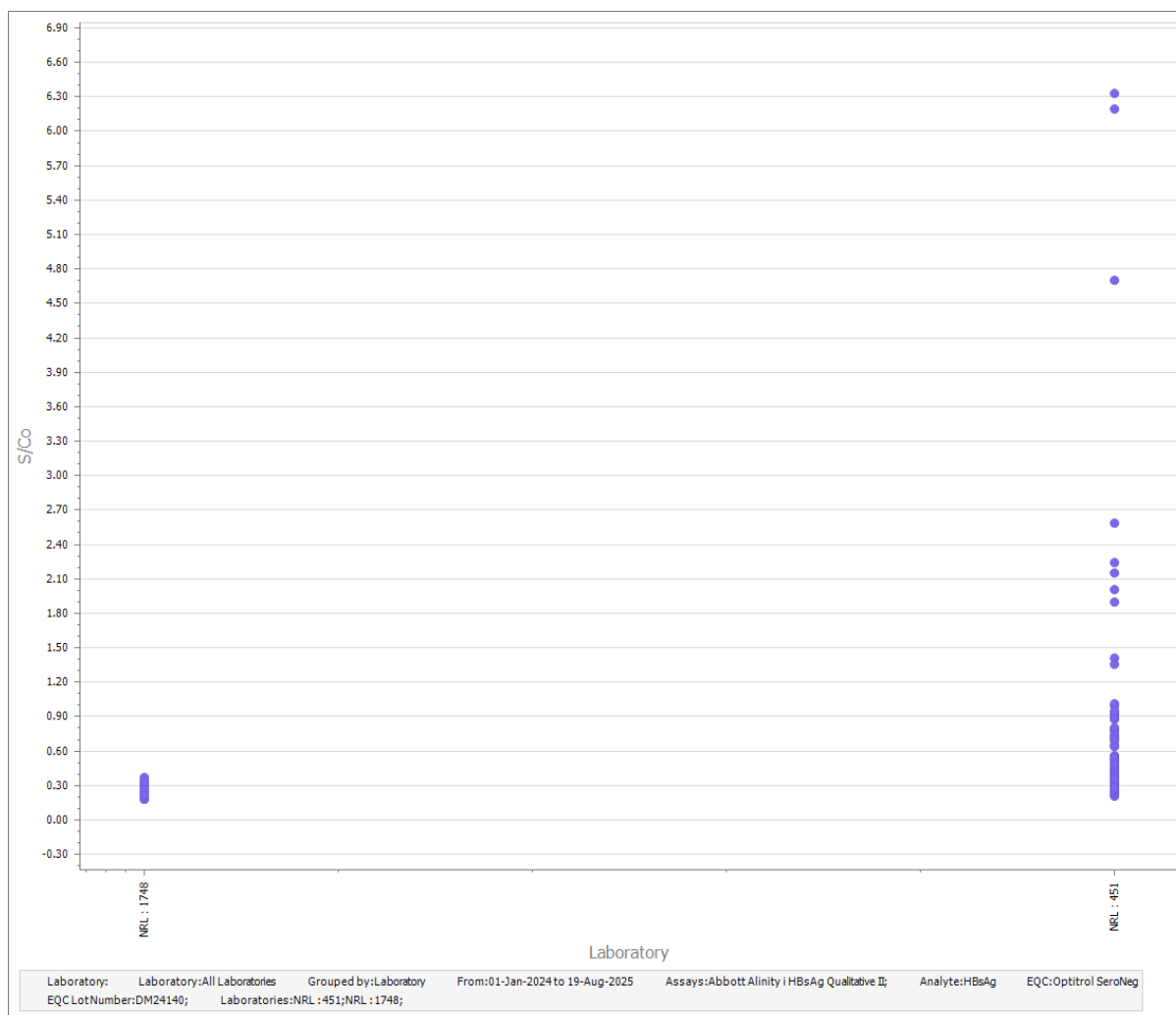


Figure 2 - Peer group data for Optitrol SeroNeg DM24140 data, reported on the Abbott Alinity i HBsAg Qualitative assay, by participant.

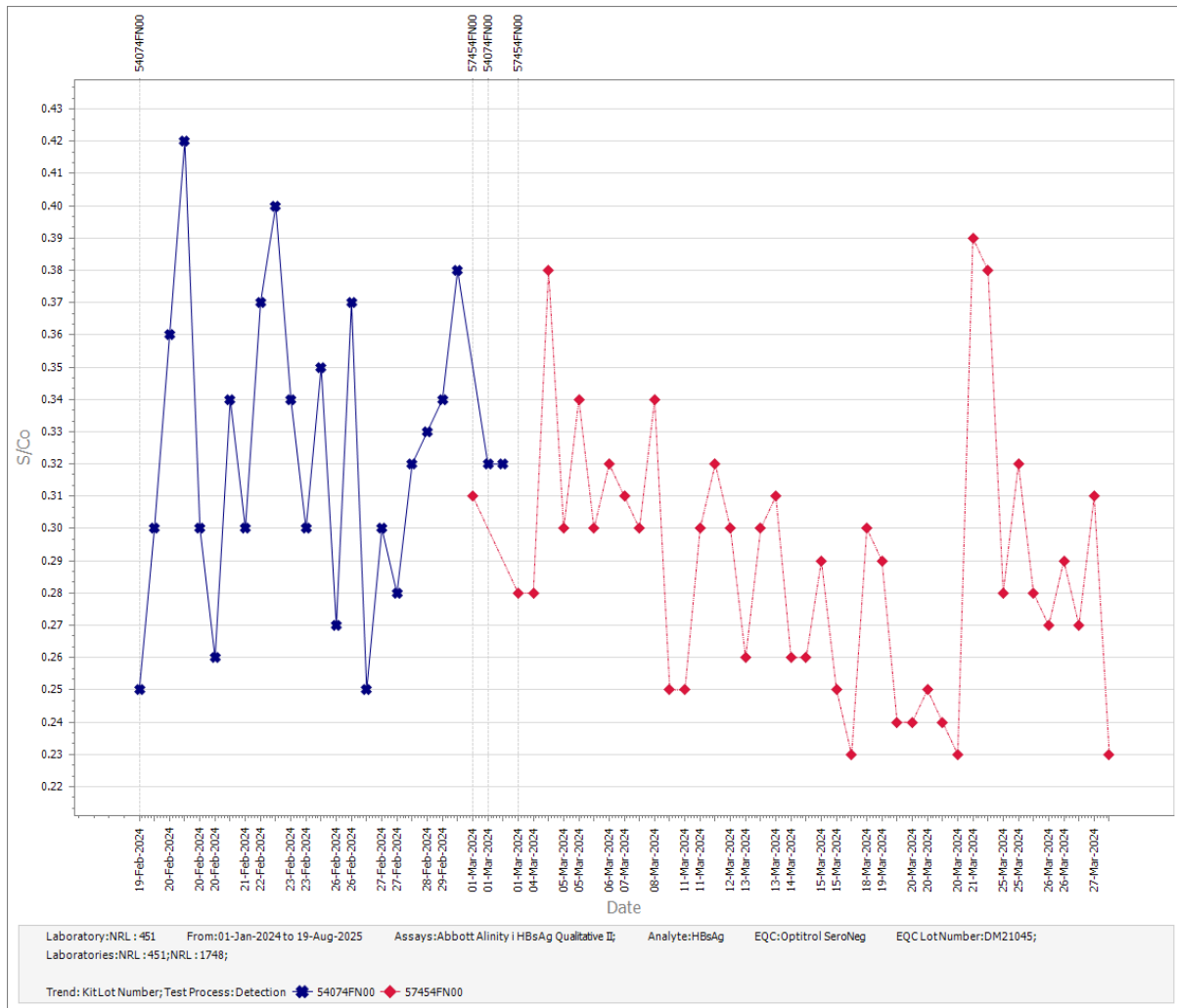


Figure 3: Participant 451 data reported for Optitrol SeroNeg DM21045 tested on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.

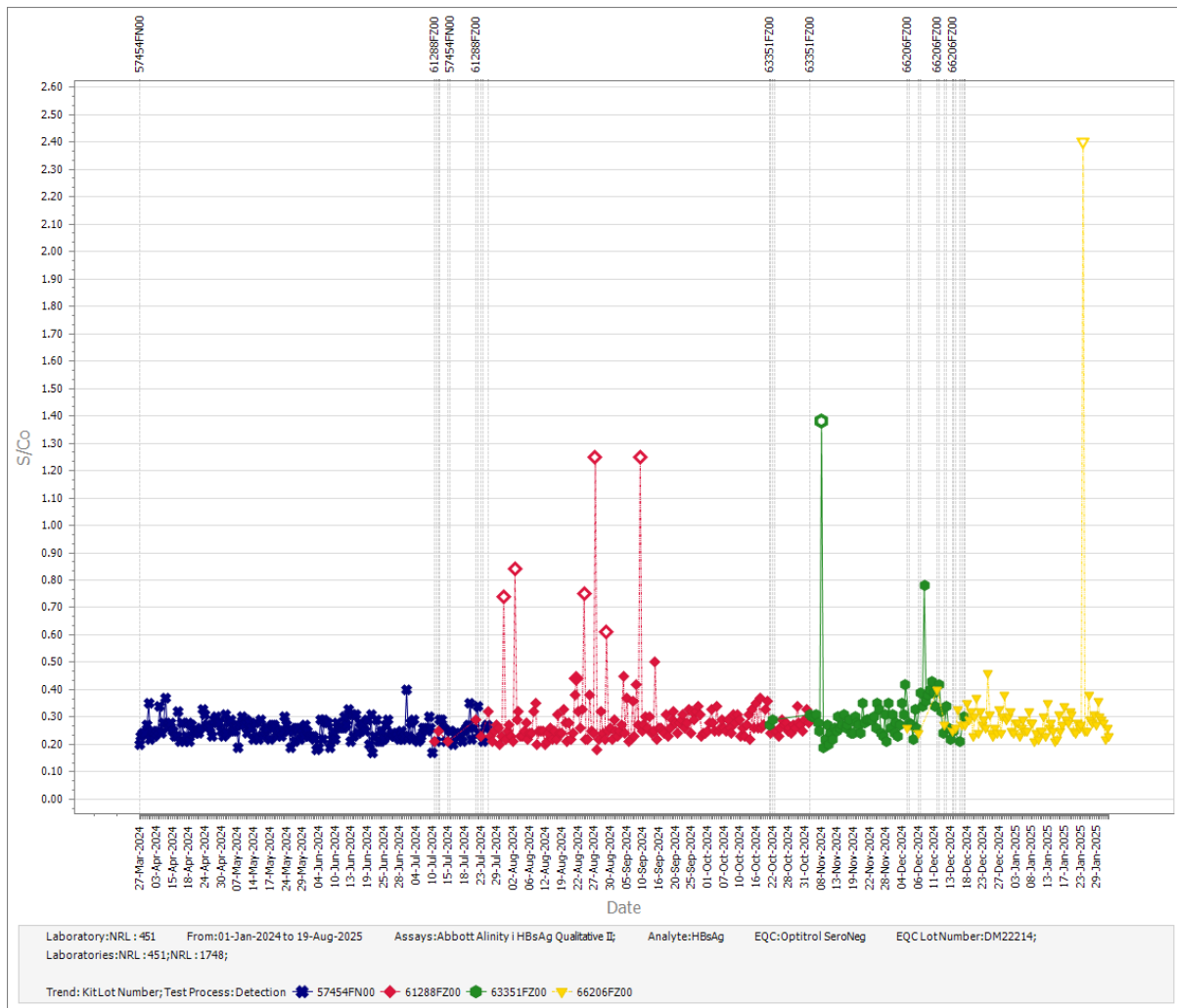


Figure 4: - Participant 451 data reported for Optitrol SeroNeg DM22214 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.

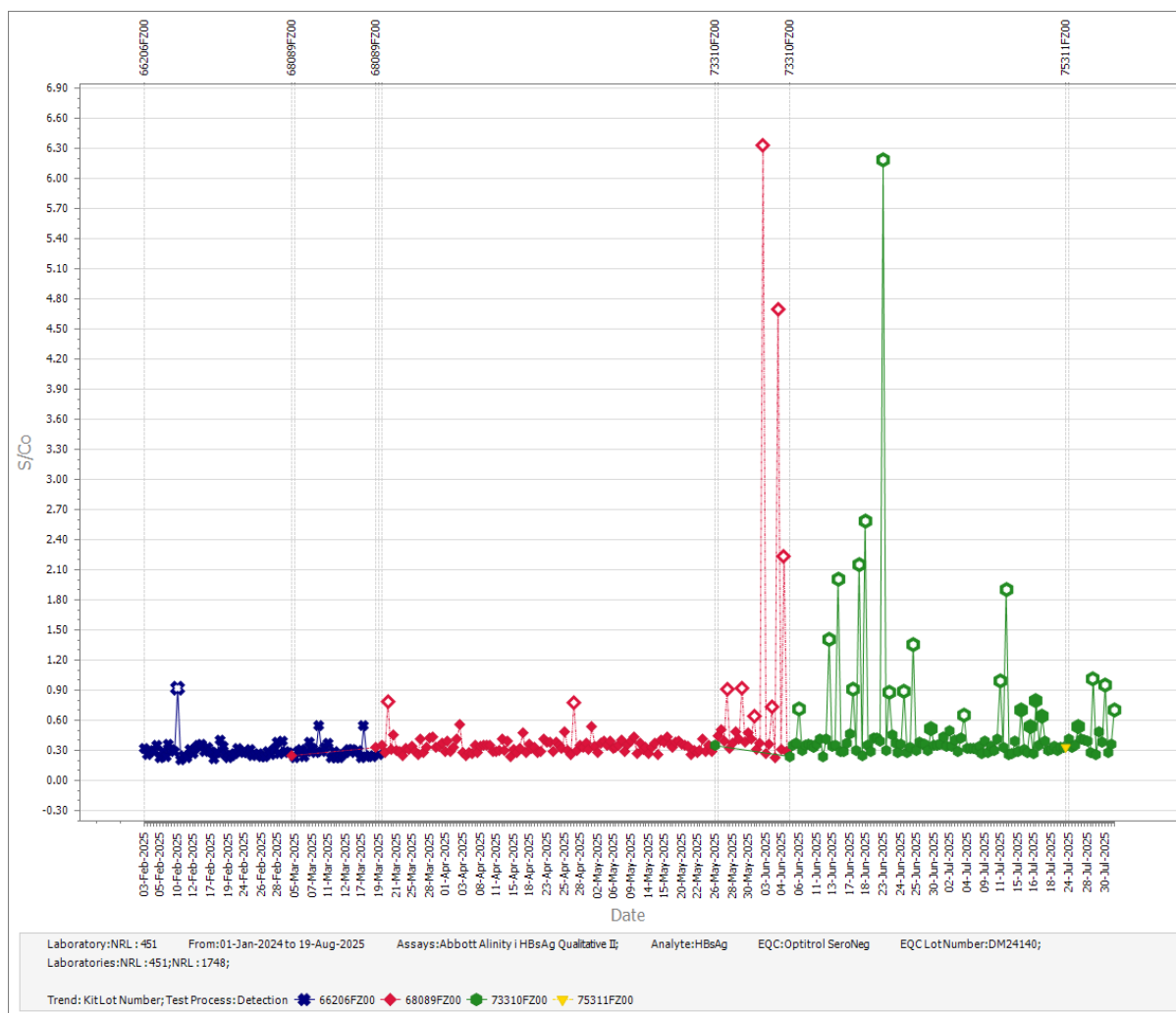


Figure 5 - Participant 451 data reported for Optitrol SeroNeg DM24140 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.

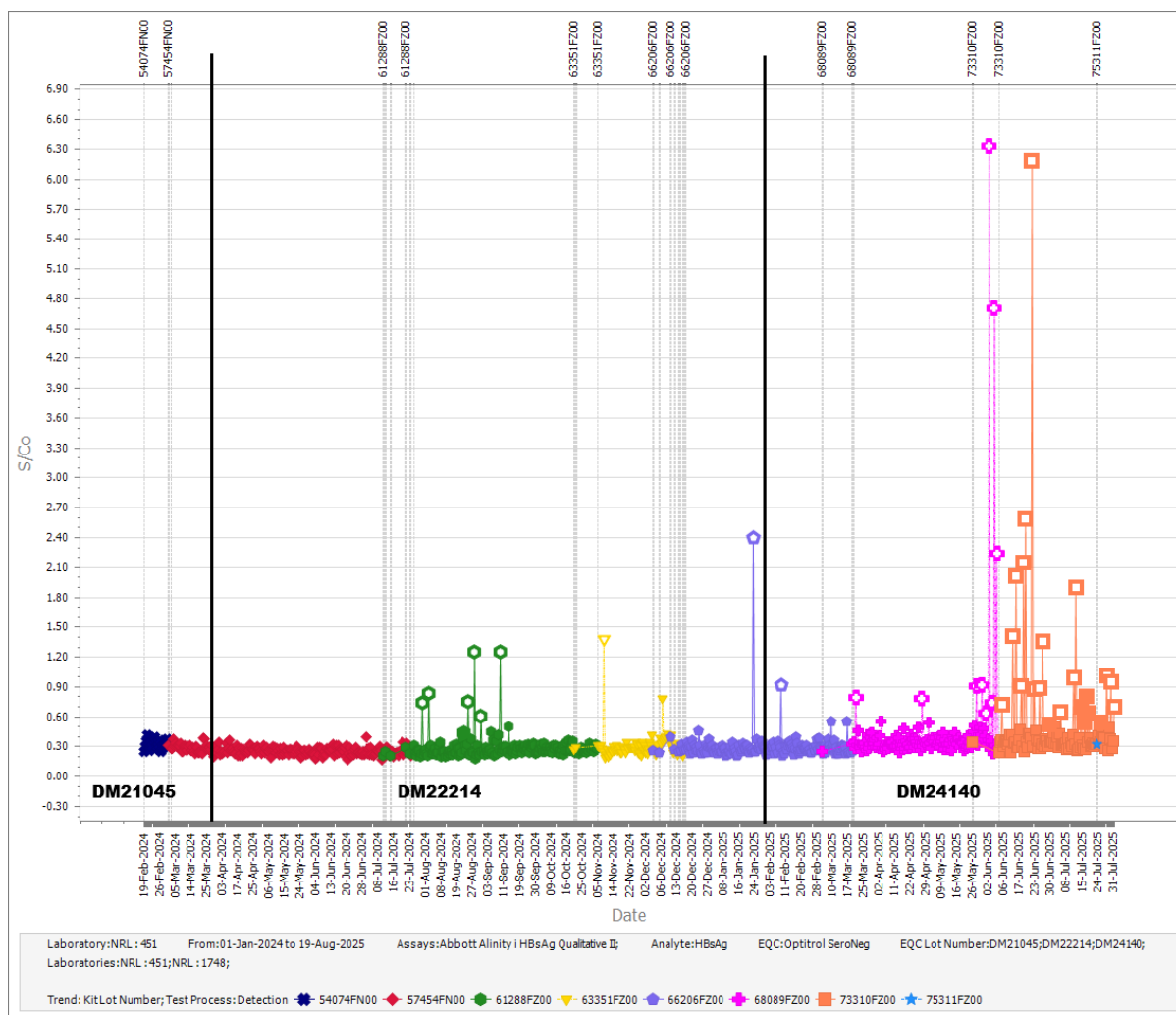


Figure 6 - Participant 451 data reported for Optitrol SeroNeg lots DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.

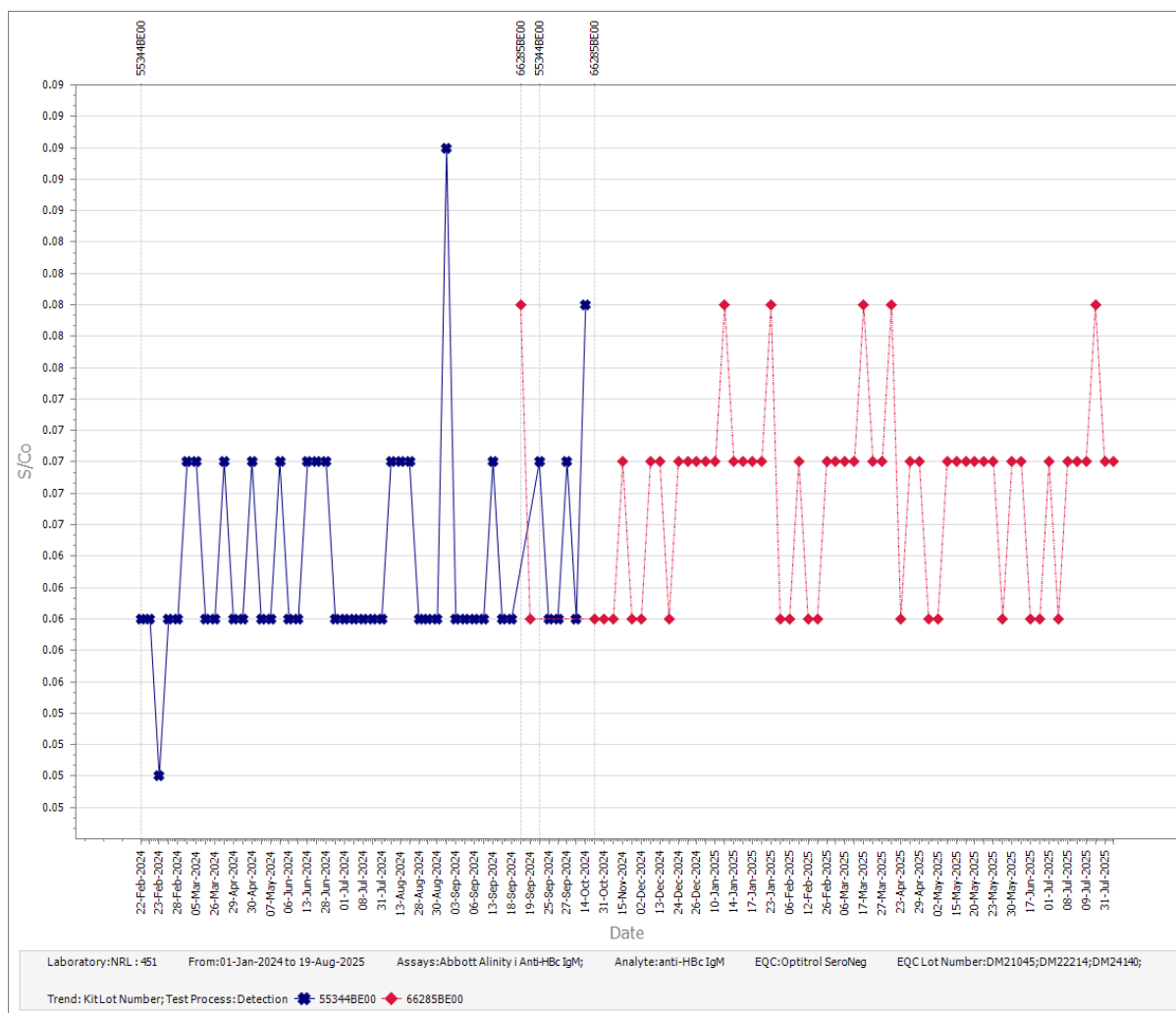


Figure 7 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HBc IgM assay.

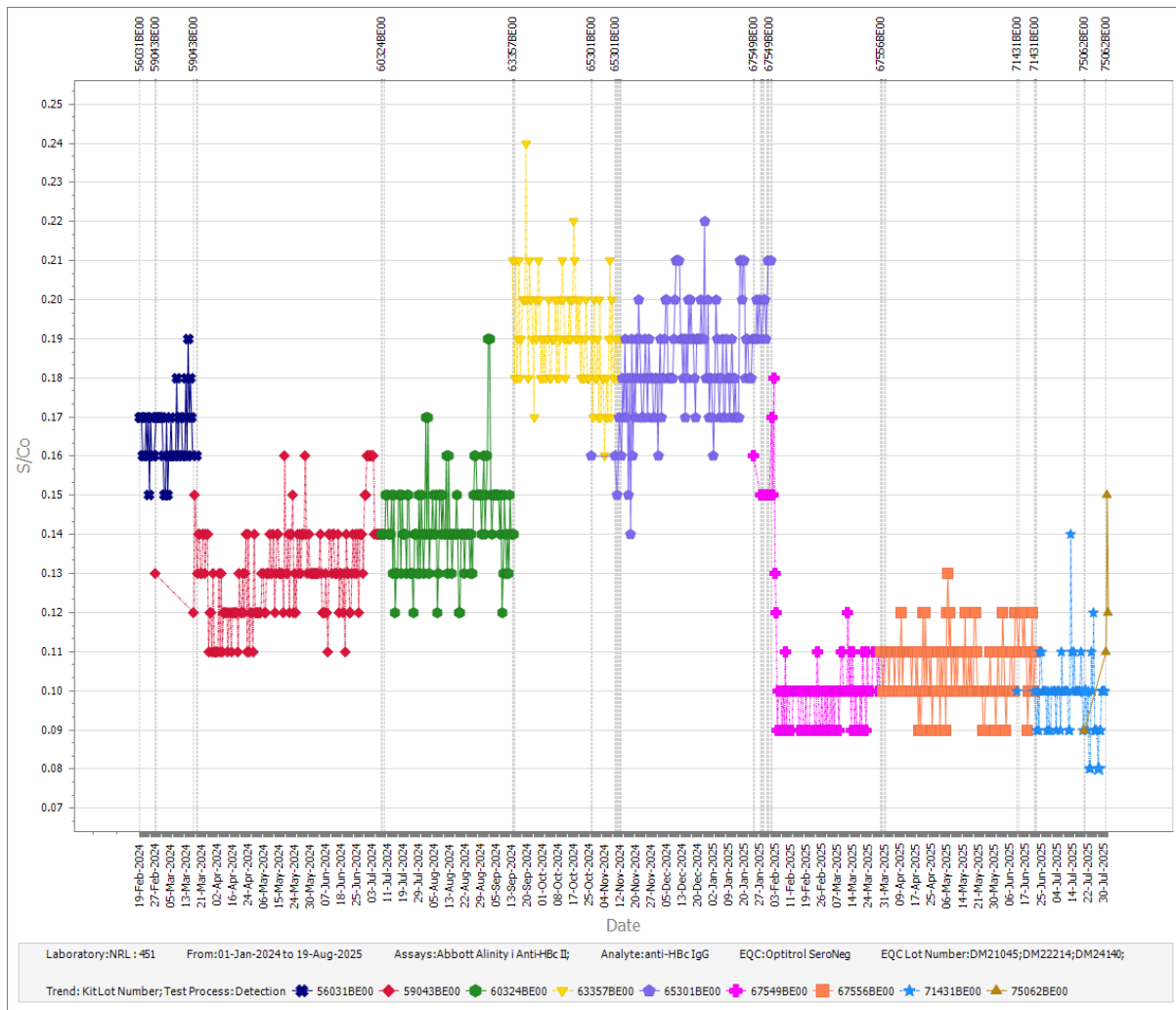


Figure 8 - Participant 451 data reported for Optitrol SeroNeg DM24145, DM22214 and DM24140 when testing on the Abbott Alinity i Anti-HBc II.

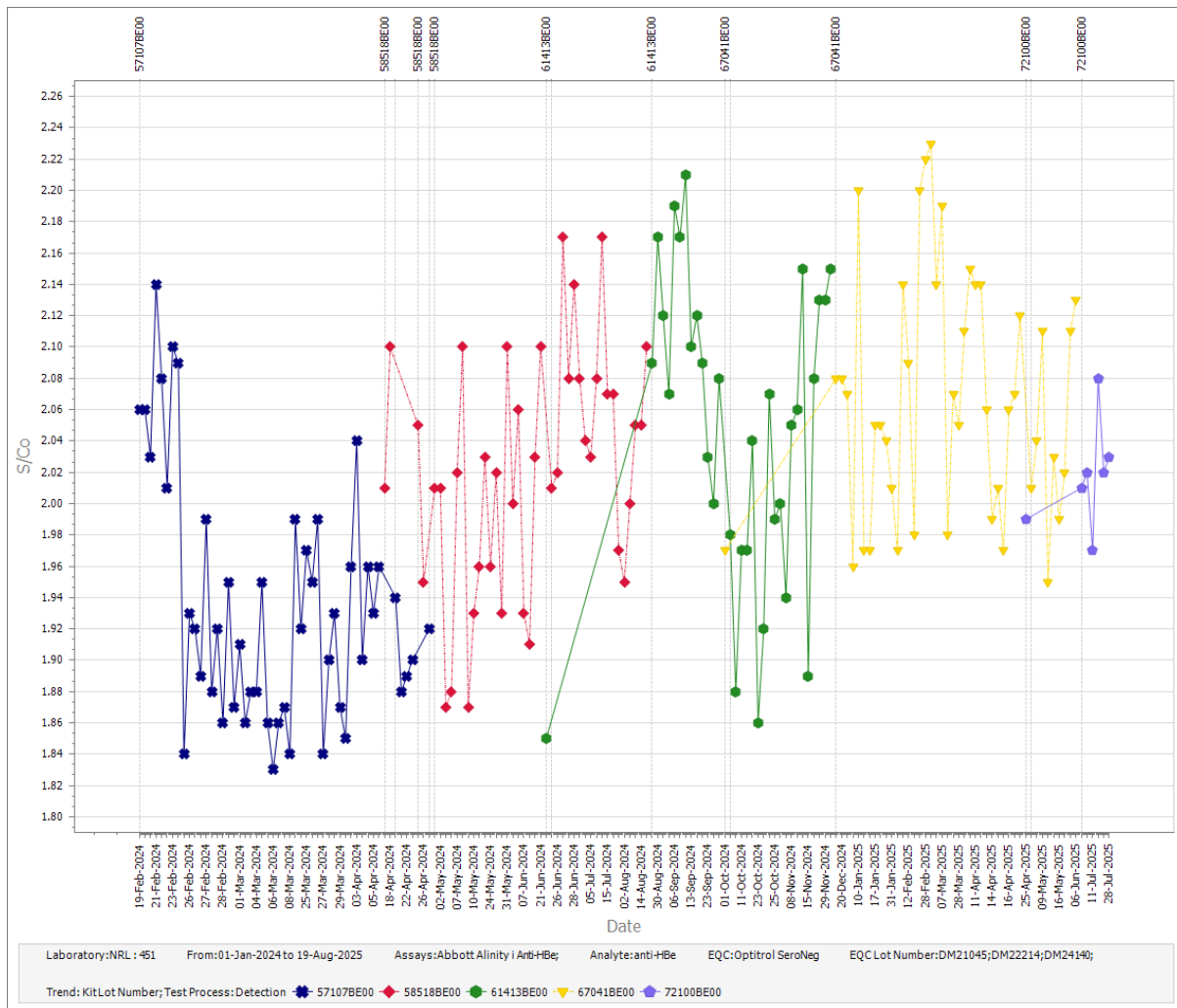


Figure 9 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HBe assay.

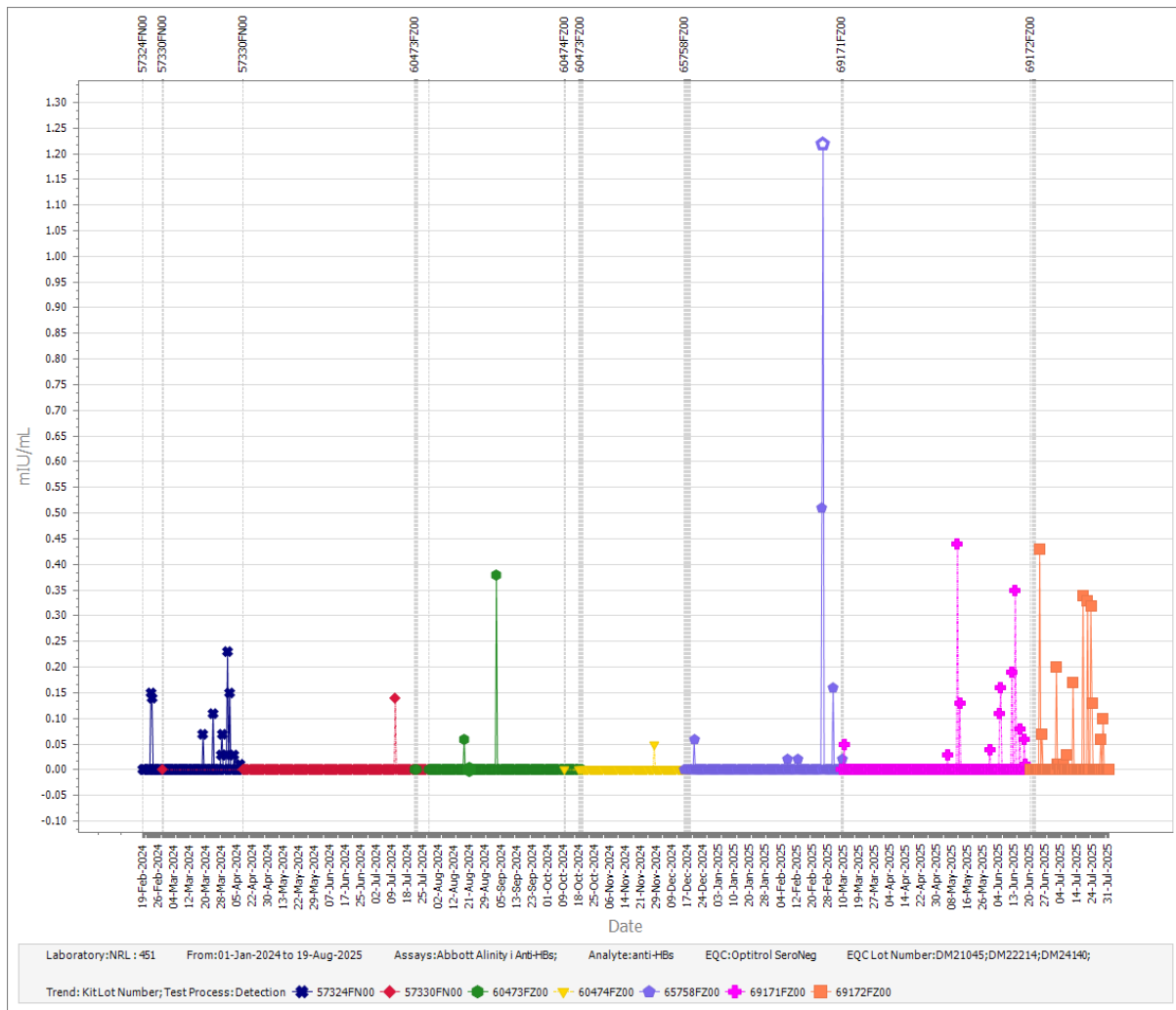


Figure 10 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 tested on the Abbott Alinity i Anti-HBs assay.

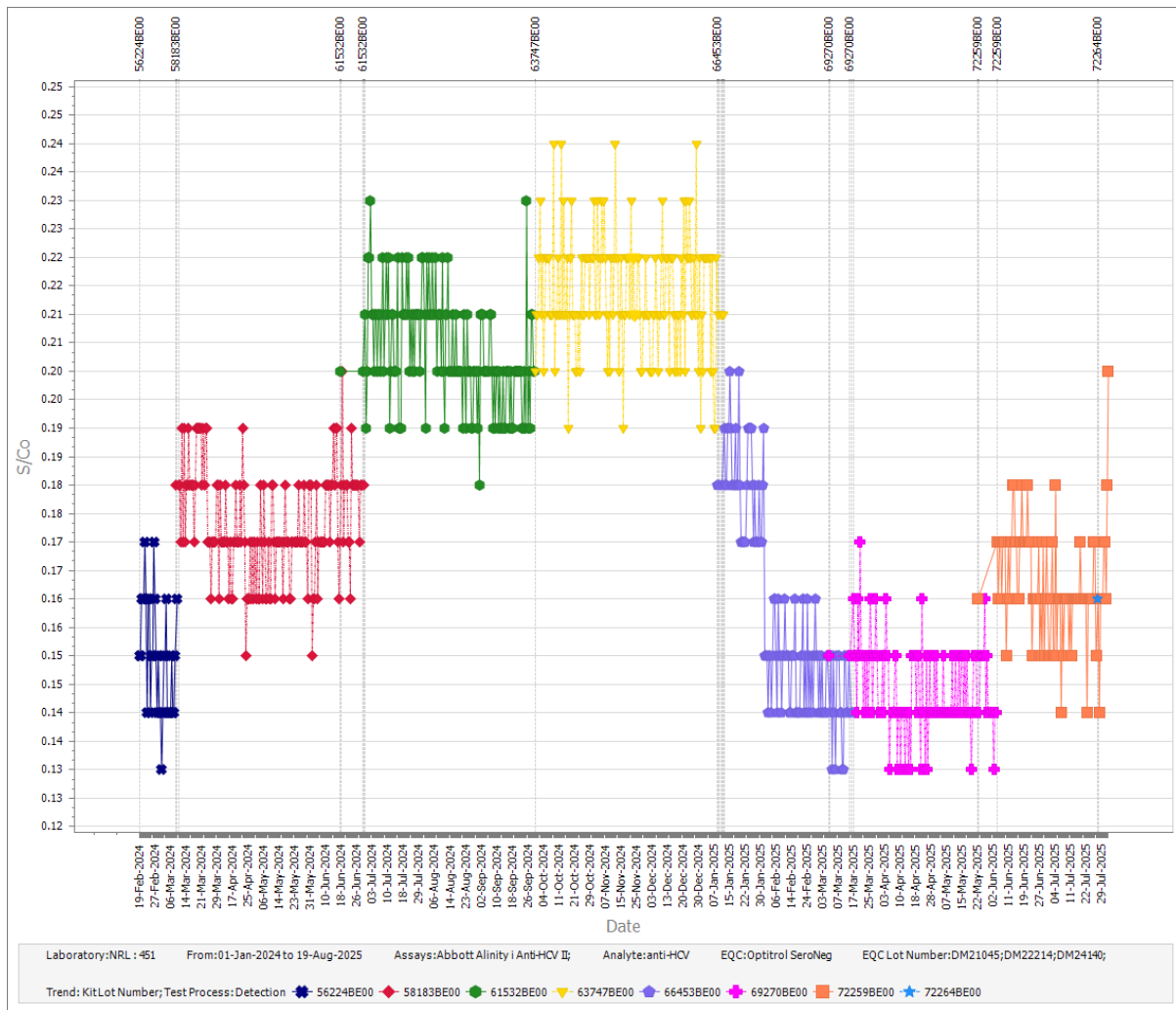


Figure 11 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i Anti-HCV II assay.

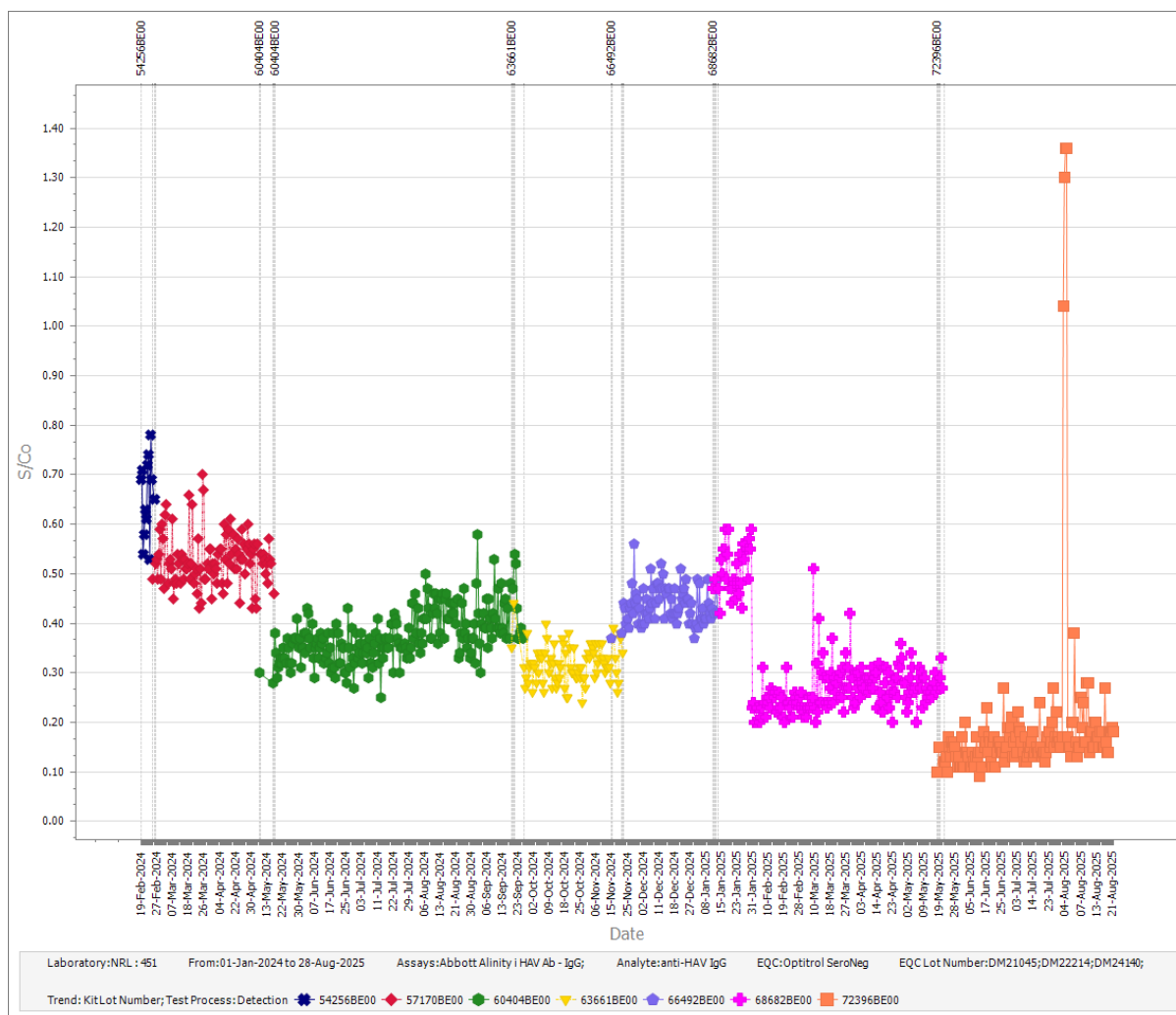


Figure 12 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HAV Ab - IgG assay.

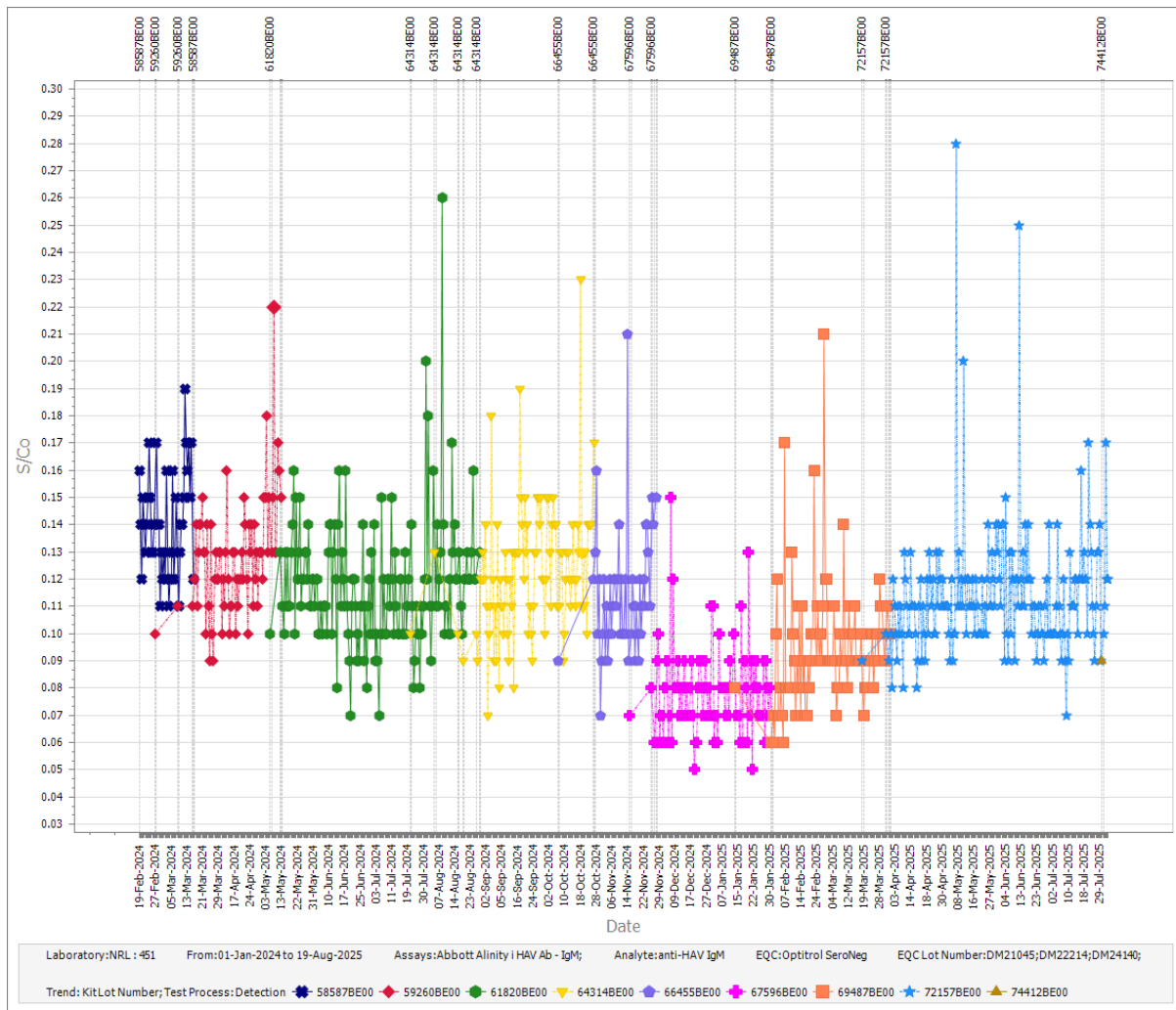


Figure 13 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HAV Ab – IgM assay.

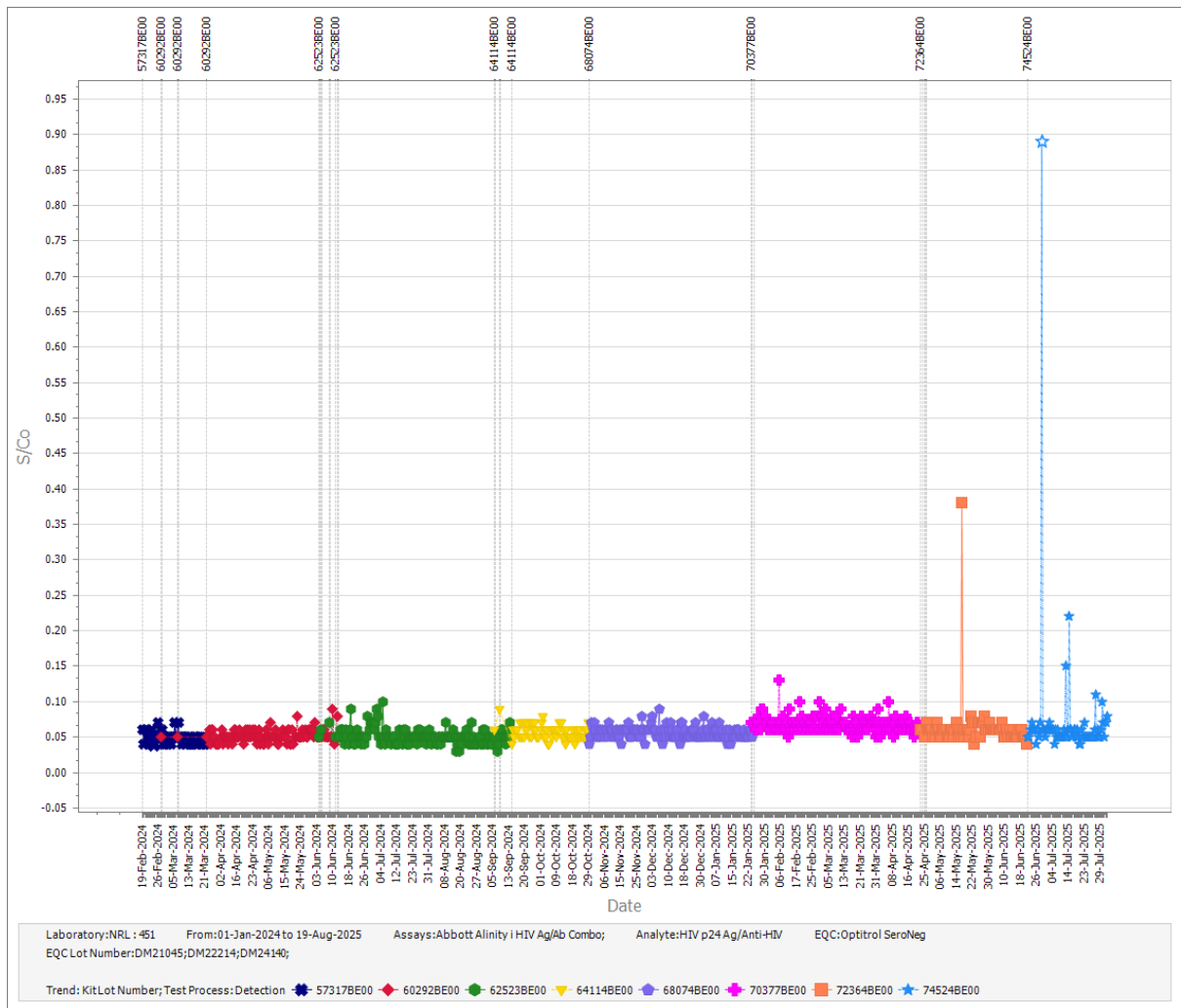


Figure 14 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i HIV Ag/Ab Combo assay.

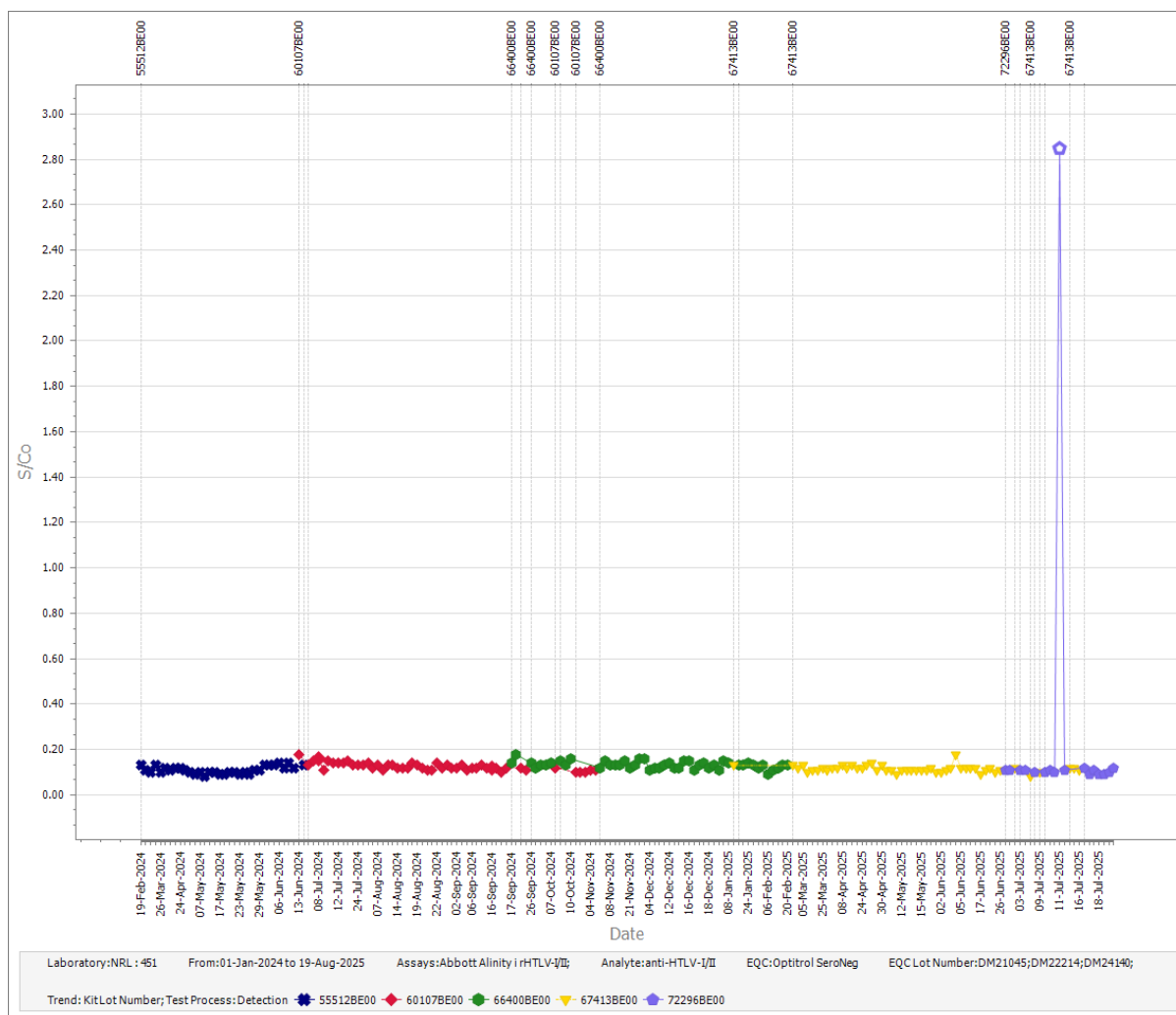


Figure 15 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i rHTLV-I/II assay.

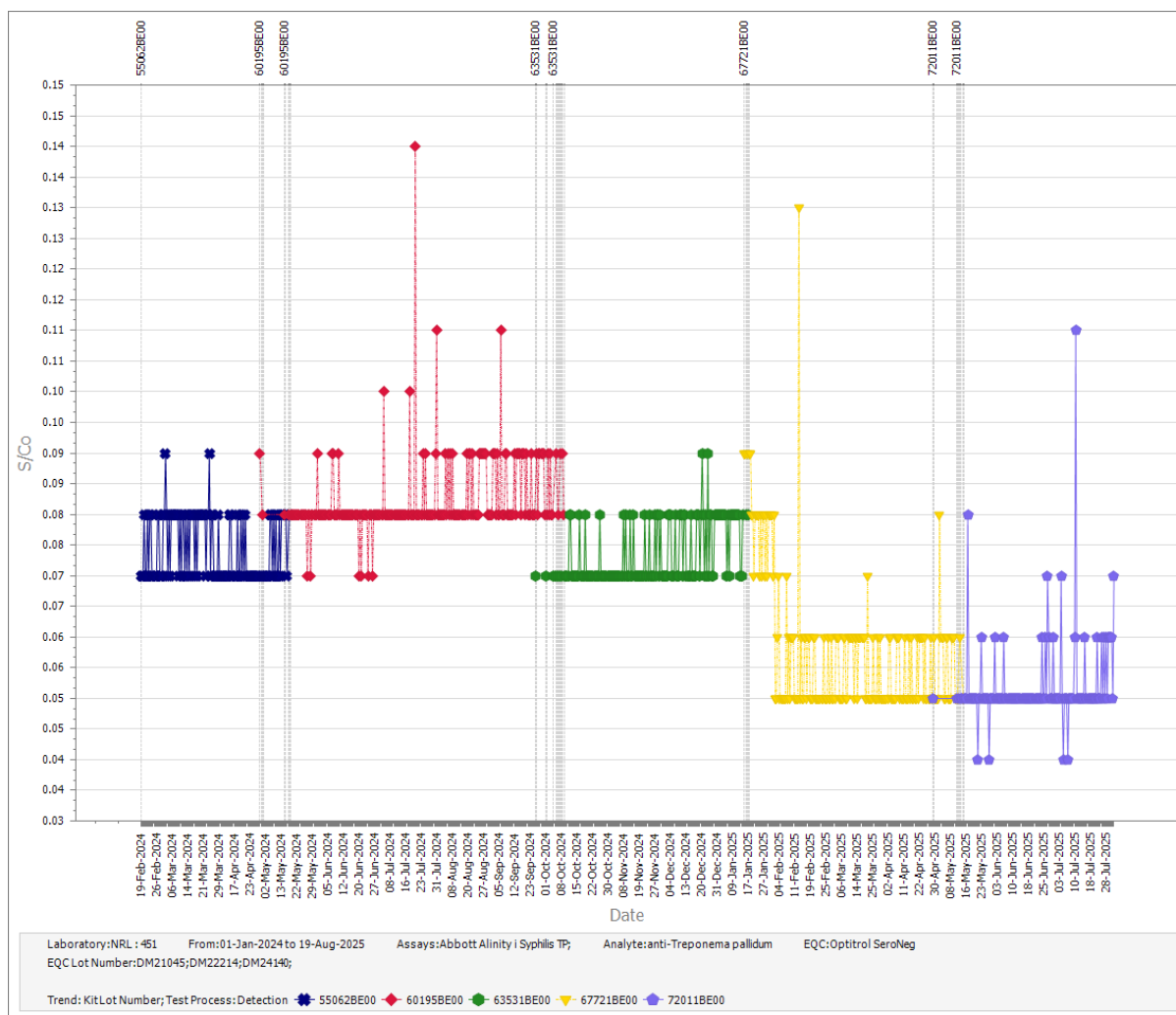


Figure 16 - Participant 451 data reported for Optitrol SeroNeg DM21045, DM22214 and DM24140 when testing on the Abbott Alinity i Syphilis TP assay.

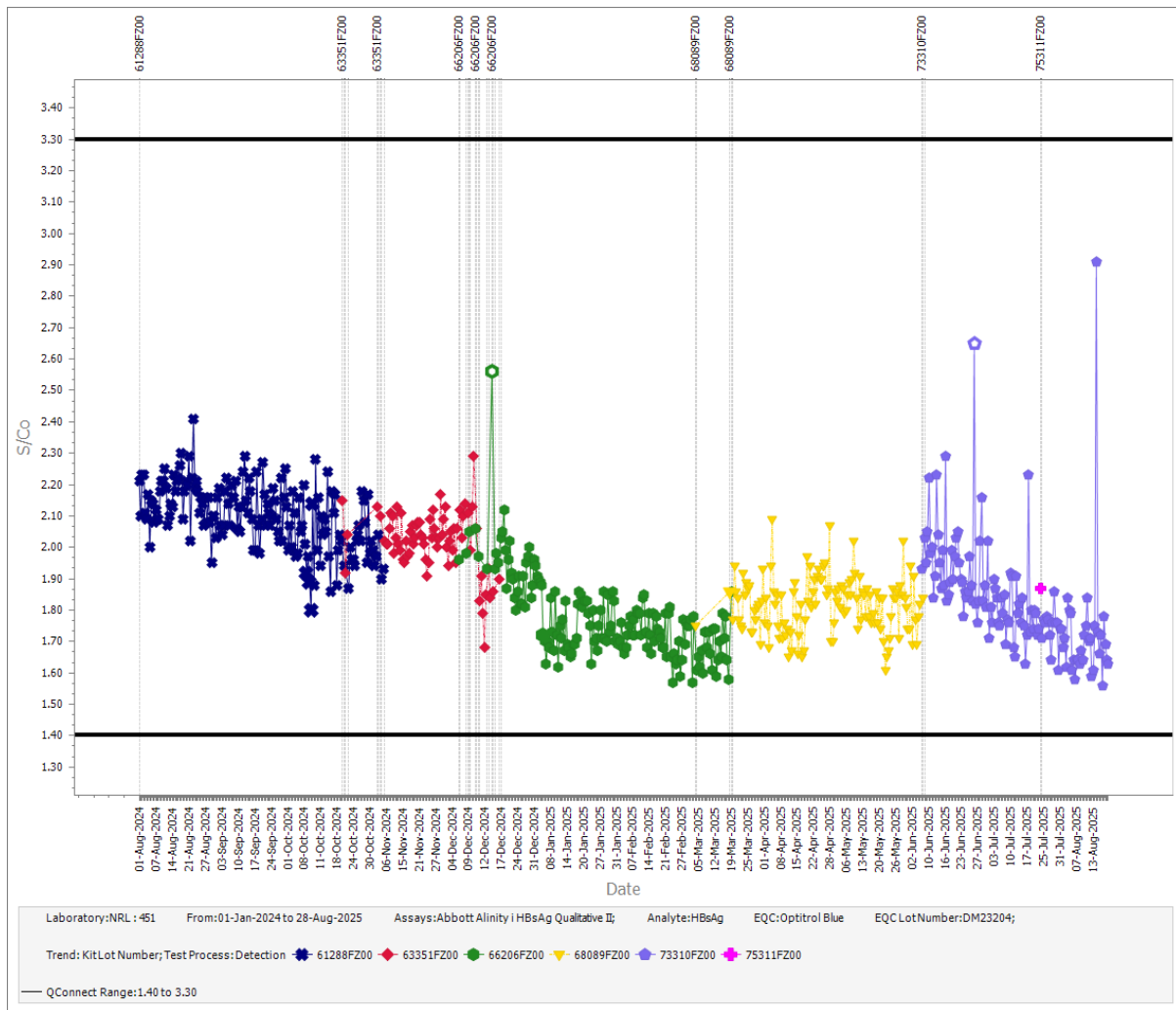


Figure 17 - Participant 451 data reported for Optitrol Blue DM23204 when testing on the Abbott Alinity i HBsAg Qualitative II assay, by reagent lot.

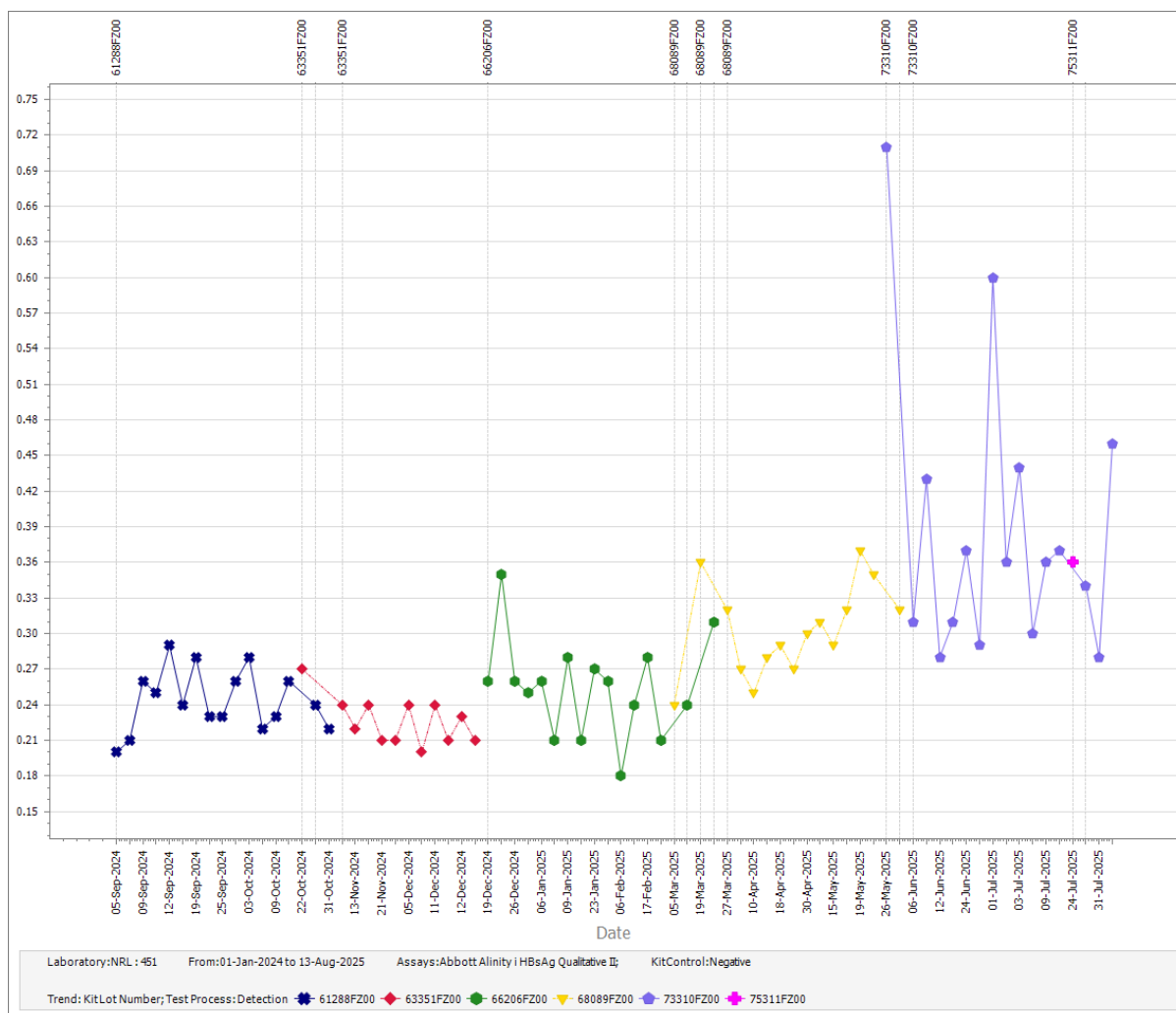


Figure 18 - Participant 451 data reported for the Abbott Negative kit control when testing in the Abbott Alinity i HBsAg Qualitative II assay.

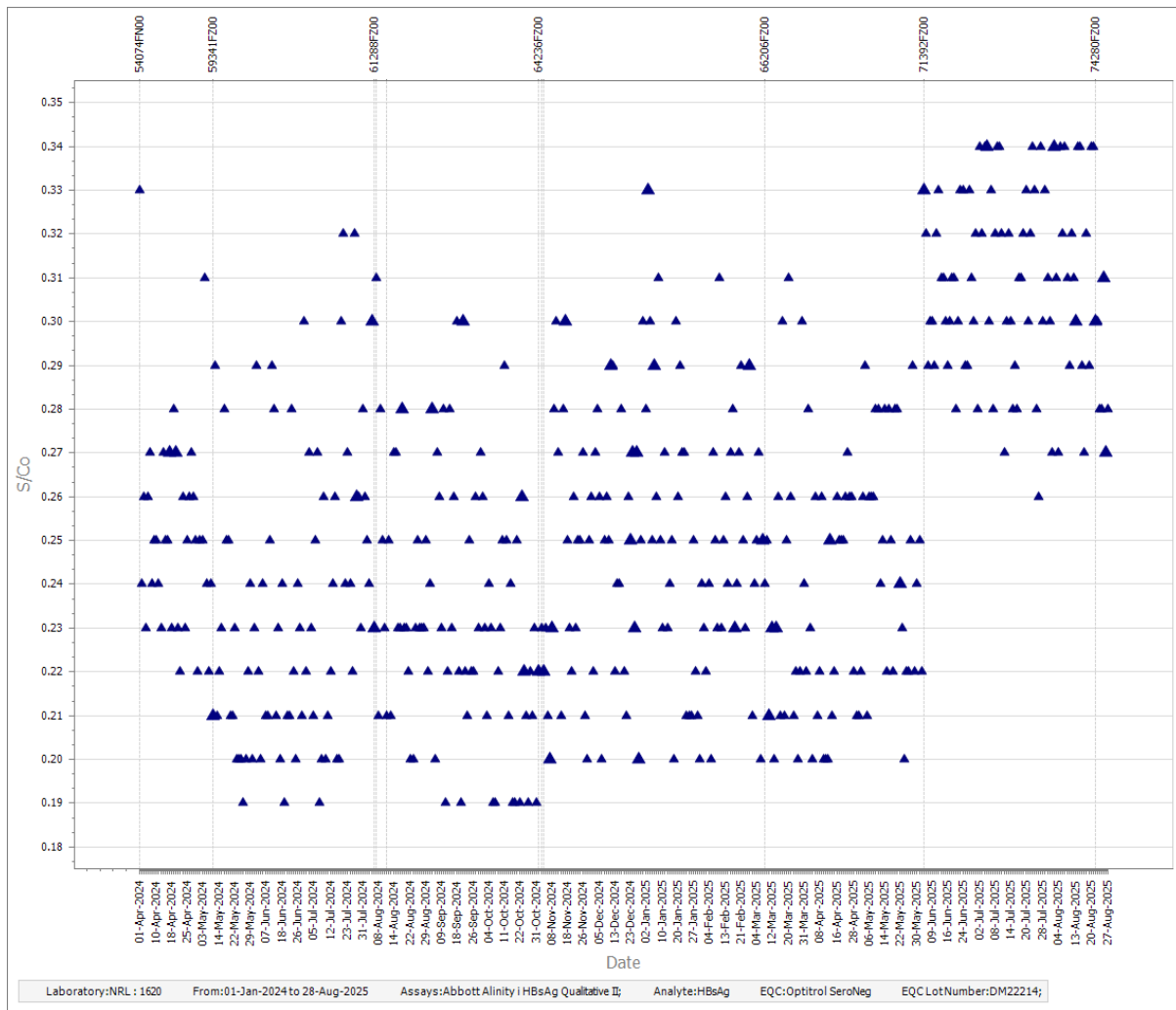


Figure 19 - Participant 1620 data reported for Optitrol SeroNeg DM24140 when testing in the Abbott Alinity i HBsAg Qualitative II assay.

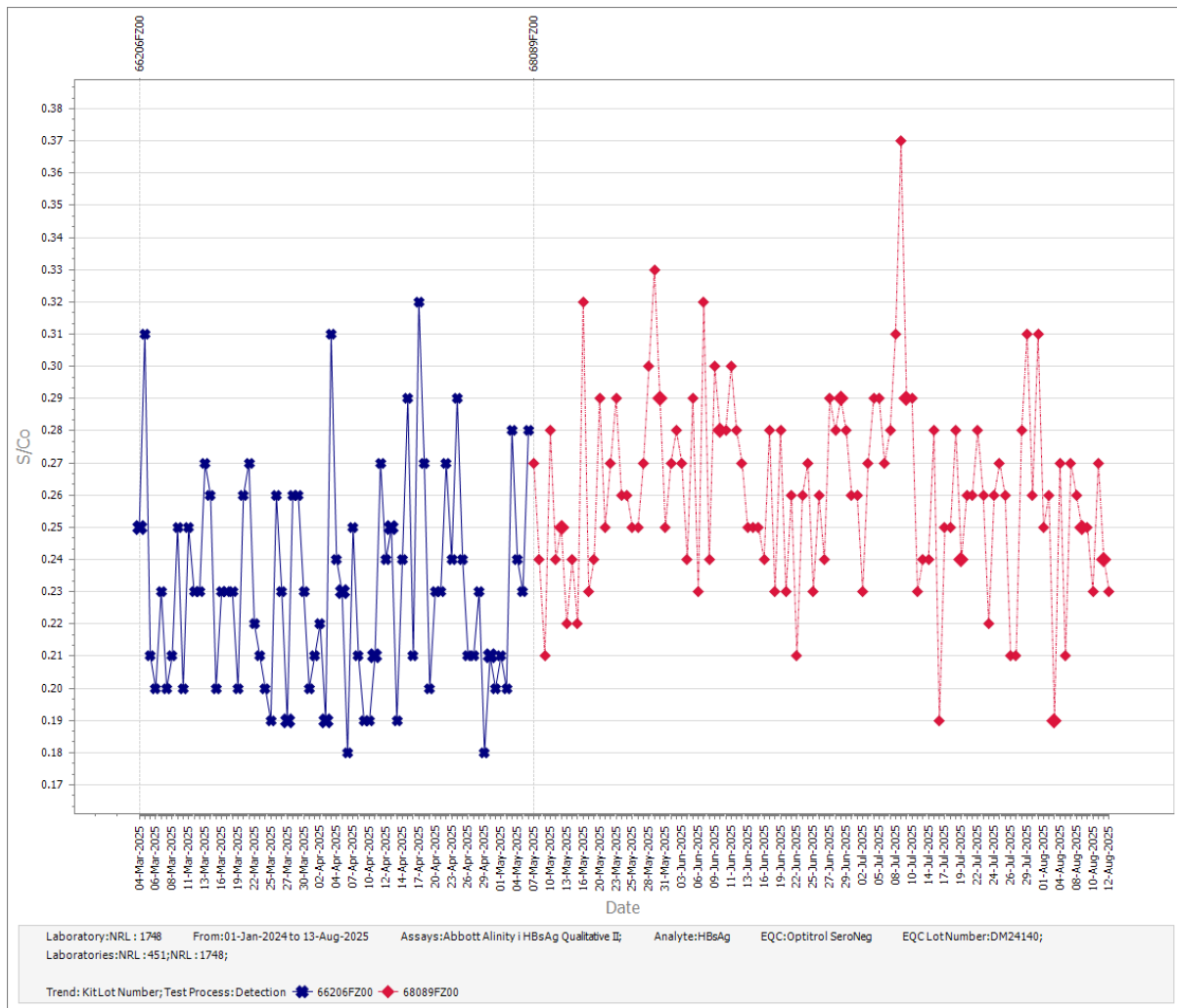


Figure 20 - Participant 1748 data reported for Optitrol SeroNeg DM24140 when testing in the Abbott Alinity i HBsAg Qualitative II assay.