

QC Services Investigation: PMM-QC-3004

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INTRODUCTION

NRL was contacted by Participant 1386 to investigate observations of ongoing multiple unexpected 'random' data reported above the upper QConnect limit for Optitrol ToRCH G DM24217 on the DiaSorin LIAISON VCA IgG assay. Participant 1386 communicated to NRL that initial schedule testing (T1) of Optitrol ToRCH G DM24217 resulted in a S/Co outside the upper QConnect Limit and repeat testing (T2) of the same sample resulted in a S/Co within QConnect Limits and consistent with expected historical results. NRL investigated all peer group for data submitted to EDCNet for all Optitrol ToRCH G lots reported on the DiaSorin LIAISON VCA IgG assay and other assays where Optitrol ToRCH G is the recommended Optitrol product for use.

FINDINGS

This investigation looked at all peer group data reported to EDCNet for all Optitrol ToRCH G lots tested on the DiaSorin and other platforms where Optitrol ToRCH G is the recommended external quality control (EQC) product of use to establish whether the pattern observed for Participant 1386 was observed for any other participant and / or assay or platform. This investigation includes data from 1 January 2025 through 28 February 2026. Below is the full list of charts included in the investigation.

- Figure 1: Participant 1386 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.
- Figure 2: Participant 1386 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 3: Participant 1386 data reported on the DiaSorin LIAISON CMV IgG II assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 4: Participant 1386 data reported on the DiaSorin LIAISON EBNA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 5: Participant 1386 data reported on the DiaSorin LIAISON Rubella IgG II assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 6: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by participant.
- Figure 7: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.
- Figure 8: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 by participant.
- Figure 9: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, by reagent lot.
- Figure 10: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM25095 by participant.
- Figure 11: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM25095 by reagent lot.
- Figure 12: Participant 8 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 and DM25095 by reagent lot.
- Figure 13: Participant 19 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.
- Figure 14: Participant 40 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 15: Participant 43 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 16: Participant 66 data reported on the DiaSorin LIAISON VCA IgG assay for

- Optitrol ToRCH G DM23186 and DM24217 by reagent lot
- Figure 17: Participant 145 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot
- Figure 18: Participant 417 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.
- Figure 19: Participant 1015 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot
- Figure 20: Participant 1354 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 21: Participant 1356 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 22: Participant 1613 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.
- Figure 23: Participant 1848 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.
- Figure 24: Participant 1853 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 25: Participant 12254 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 26: Participant 2288 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.
- Figure 27: Participant 2288 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.
- Figure 28: Participant 2357 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.
- Figure 29: Participant 1425 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.
- Figure 30: Participant 1615 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.
- Figure 31: Participant 1751 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.

DISCUSSION

Figures 1 & 2 show Participant 1386 data demonstrating the performance and observation of increased variation between T1 and T2 daily testing of Optitrol ToRCH G lot DM24217 and Optitrol ToRCH G lots DM23186 and DM24217, respectively, when tested on the DiaSorin LIAISON VCA IgG assay by reagent lot.

Figures 3, 4 and 5 show Participant 1386 data for Optitrol ToRCH G lots DM23186 and DM24217 for all other DiaSorin assays, DiaSorin LIAISON CMV IgG II, EBNA IgG and Rubella IgG, reported by the participant also testing with Optitrol ToRCH G DM23186 and DM24217. No observation of increased variation was observed for these assays.

Figures 6 & 7, 8 & 9 and 10 & 11 show the DiaSorin LIAISON VCA IgG assay peer group reported for Optitrol ToRCH G DM24217, DM23186 and DM25095 by participant and reagent lot, respectively.

Optitrol ToRCH G DM24217 was reported by 18 participants testing across 8 reagent lots (Figures 3 and 4). Only one reagent lot (311035) did not illustrate the same increased variation pattern identified by Participant 1386. This could be due to less data having been reported on this reagent lot compared to others in use.

Optitrol ToRCH G DM23186 was reported by 18 participants testing across 8 reagent lots,

(Figures 5 and 6). Seven of the eight reagent lots (311027, 3110298, 311029, 311030, 311031, 311032 and 311033) in use with DM23186 were also reported in use with DM24217. The observation of increased or unexpected variation was not observed for data reported for Optitrol DM23186.

Figure 22 show Participant 1613 data reported for Optitrol ToRCH G DM23186, DM24217 and DM25095 on the DiaSorin LIAISON VCA IgG assay. Data reported above the upper QConnect range for Optitrol DM23186 were investigated (PMM-QC-2482) and were found to be a result of an instrument issue and not related to this investigation.

Optitrol ToRCH G DM25095 was reported across nine participants testing on five reagent lots (Figures 7 and 8). All five reagent lots (311030, 311031, 311032, 311033 and 3110350) in use with DM25095 were also reported in use with DM24217. The same increased variation observed for all reagent lots and similarly the only reagent lot which this variation was not observed (311035) could be due to less data having been reported on this reagent lot compared to others in use.

Figures 12 through 31 show individual participant data reported on the DiaSorin LIAISON VCA IgG assay for all Optitrol ToRCH G lots in use for each participant. There were 21 participants, including Participant 1386, that reported data for Optitrol ToRCH G on the DiaSorin LIAISON VCA IgG assay during the period under review. Of these participants, 18 reported data for both Optitrol ToRCH G DM23186 and DM24214 and seven of these (Participants 8, 43, 417, 1386, 1848, 2254 and 2288) were identified to have reported a similar pattern of increased variation as reported by Participant 1386. Nine participants reported data for Optitrol ToRCH G DM25095. Of these participants, five (Participants 8, 417, 425, 1615 and 2288), were observed to have a similar pattern of increased variation under investigation. Three participants (1425, 1615 and 1751) had not reported data for Optitrol ToRCH G DM24214 and only Participant 1751 data did not show a similar pattern of variation, this could be due to the smaller number of data reported.

Four Participants (8, 417, 1848 and 2288) had reported data for both Optitrol ToRCH G lots DM24217 and DM25095. All but one (Participant 1848) showed the same pattern of variation across both Optitrol ToRCH G lots as reported by Participant 1386.

NRL were made aware that Optitrol ToRCH G lot DM24217 was manufactured with new EBV stock material which required an increase in dilution factor for analytes EBV and EBNA. This dilution factor was decreased again for the manufacture of Optitrol ToRCH G DM25095. The same EBV stock material was used in both QC lots.

CONCLUSIONS

The pattern of T1 and T2 testing resulting in increased variation reported by Participant 1386 was observed for both Optitrol ToRCH G lots, DM24214 and DM25095 reported across the peer group. Data reported for Optitrol ToRCH G DM23186 did not illustrate a similar pattern of variation for any participant or reagent lot within the peer group.

There was no observation of this pattern of variation for other DiaSorin assays where Optitrol ToRCH G DM23186, DM24214 and / or DM25095 were reported.

Initial observations indicate the change EBV Stock material used in the manufacture of Optitrol ToRCH G from lot DM24217 may have contributed to the change in the S/Co values reported for this Optitrol product. However, the observed inconsistency of this pattern of variation reported across the peer group, where only seven participants out of a peer group of 21 reported data showing the same pattern of variation reported by Participant 1386, indicating further investigation is required.

RECOMMENDATIONS

NRL recommend participants report all data to EDCNet.

NRL recommends participants add relevant comments, for example, T1 or sample to be repeated, in EDCNet for reference and traceability.

NRL will contact all members of the Peer group where this pattern of variation was not identified here, to confirm data reported and / or obtain any unreported data for review.

NRL will contact all members of the Peer group requesting information on their order of testing and testing algorithm pattern to investigate if this indicates a possible root cause.

NRL will share this report with LGC Diagnostic INC. for review and further investigation in partnership with NRL and DiaSorin S.p.A if required.

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

APPENDIX

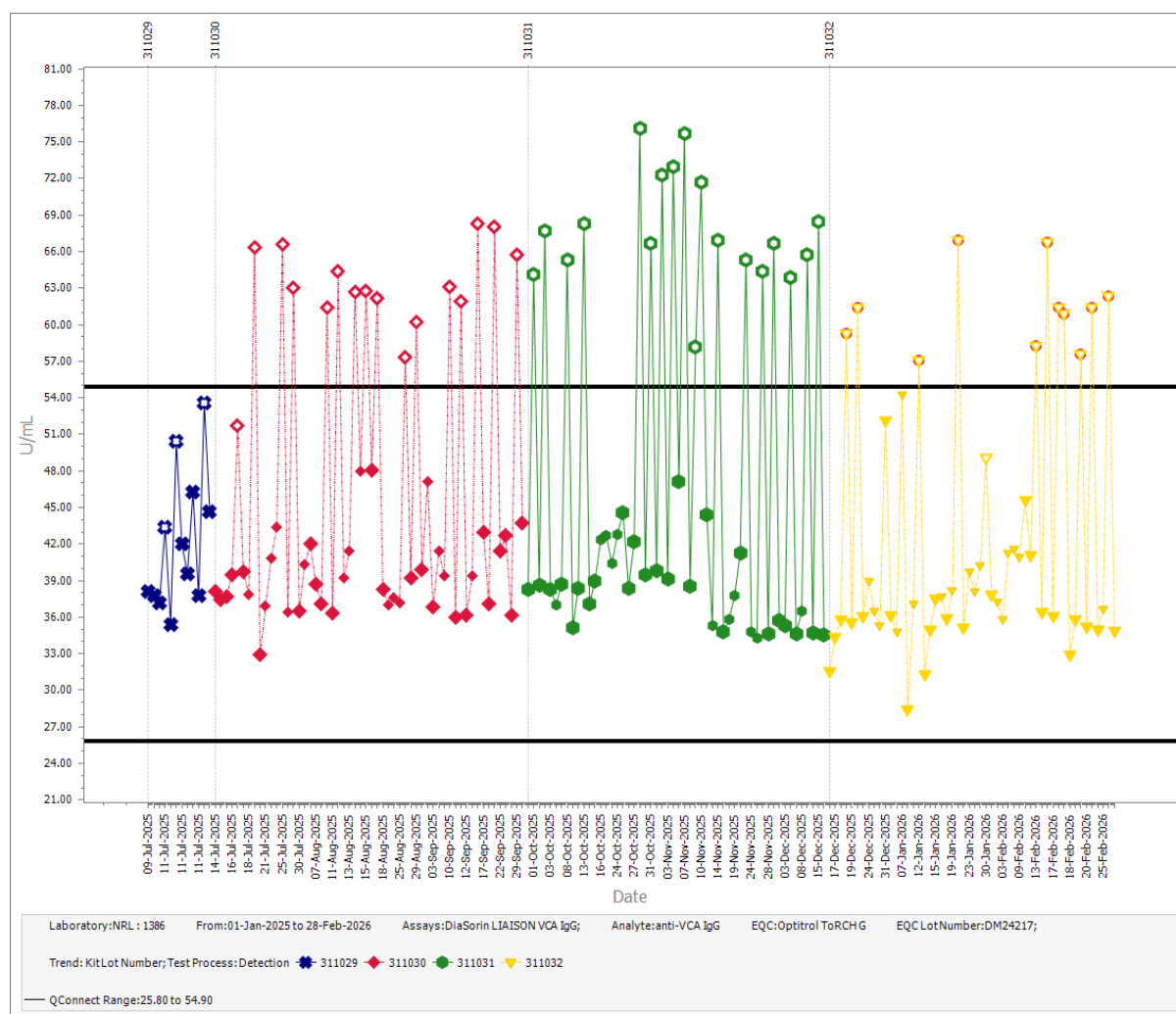


Figure 1: Participant 1386 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.

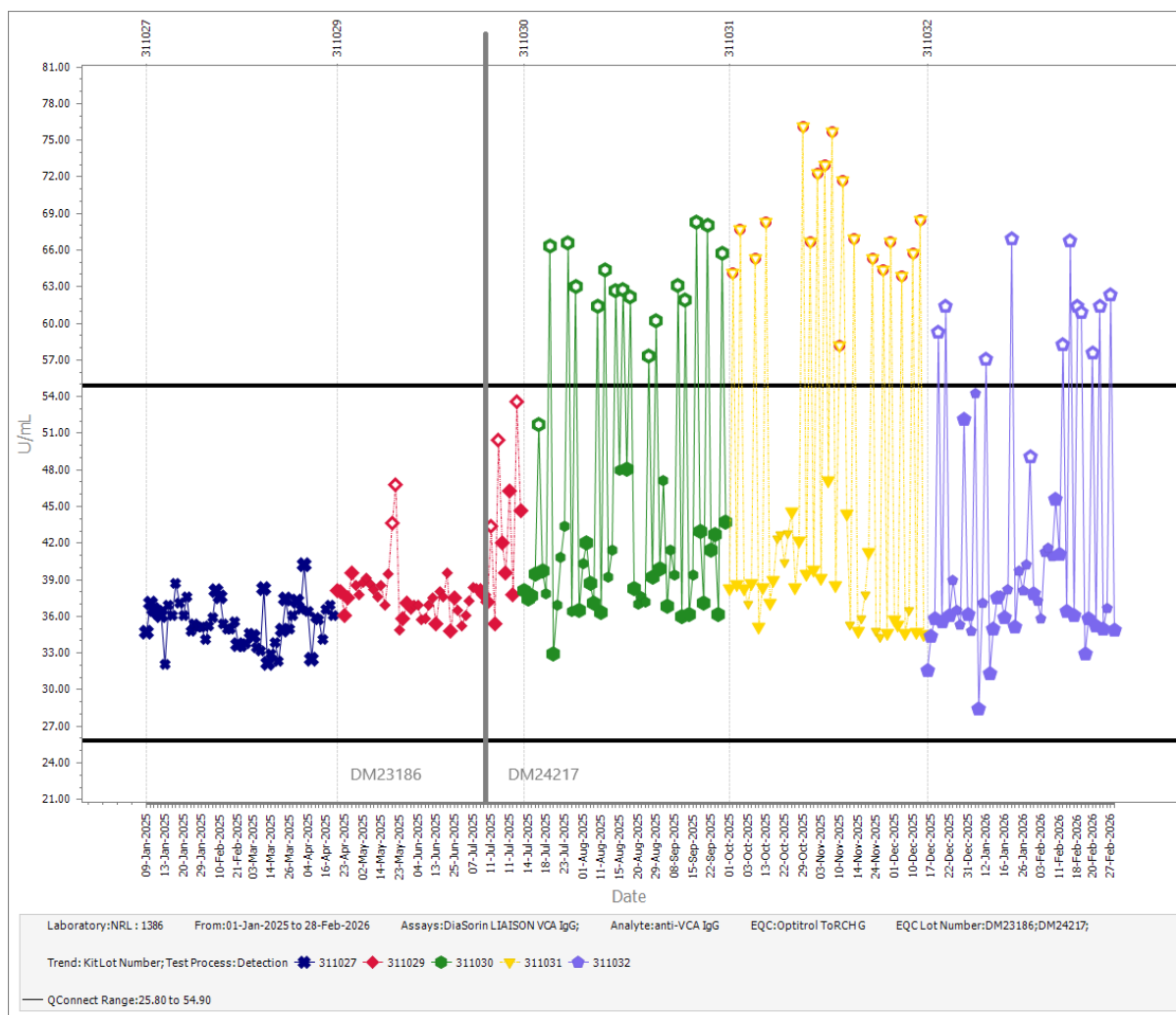


Figure 2: Participant 1386 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

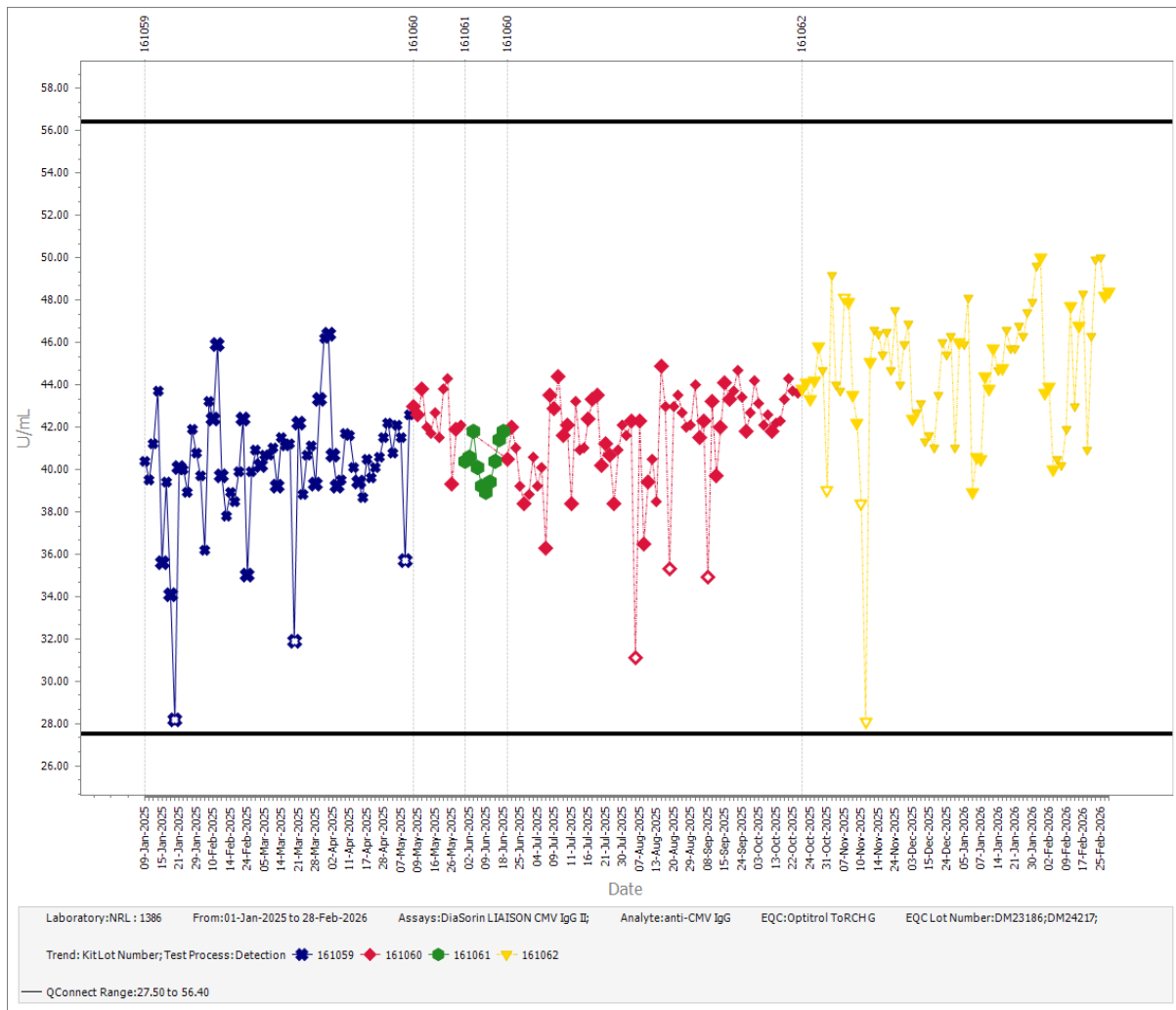


Figure 3: Participant 1386 data reported on the DiaSorin LIAISON CMV IgG II assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

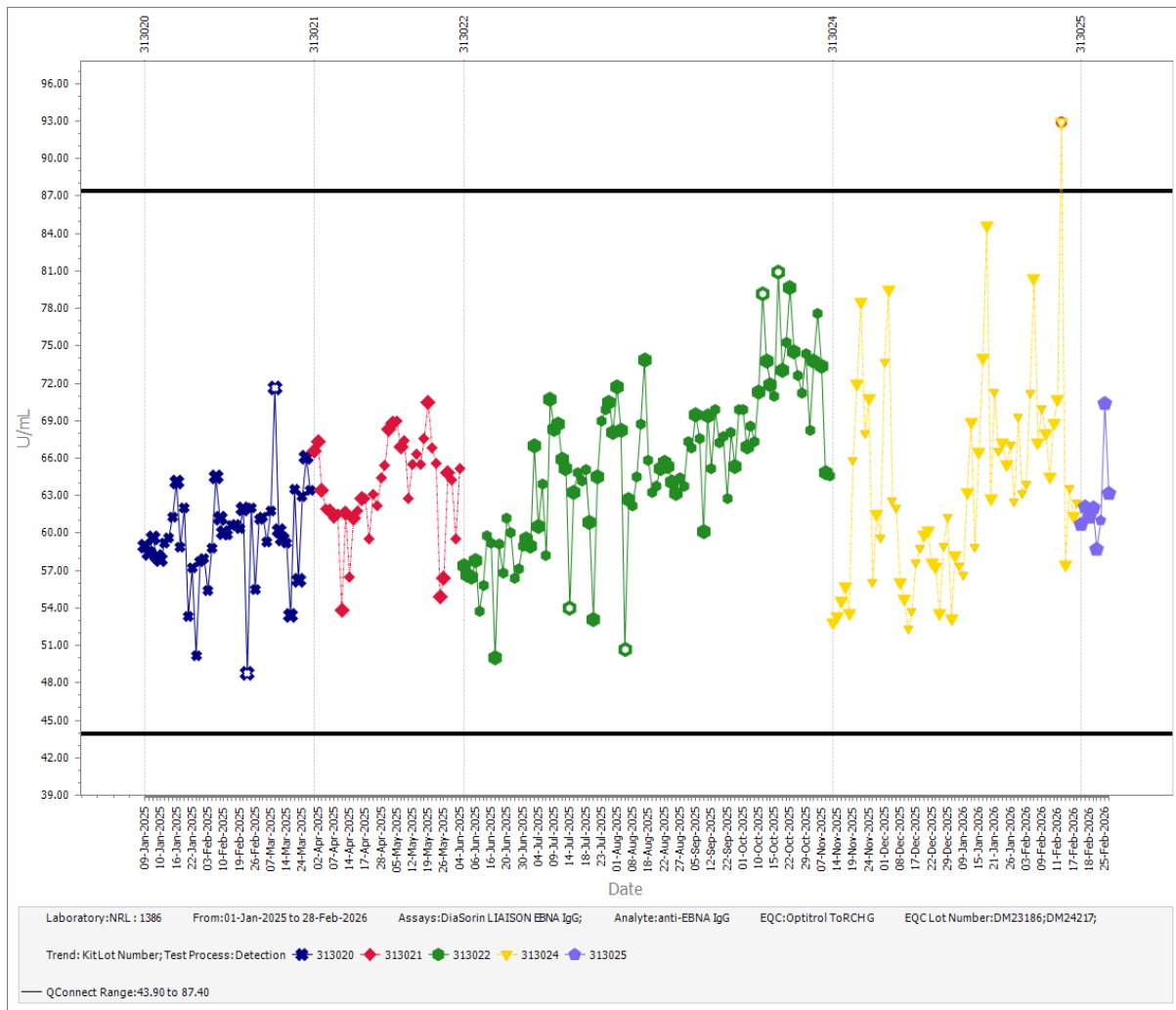


Figure 4: Participant 1386 data reported on the DiaSorin LIAISON EBNA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

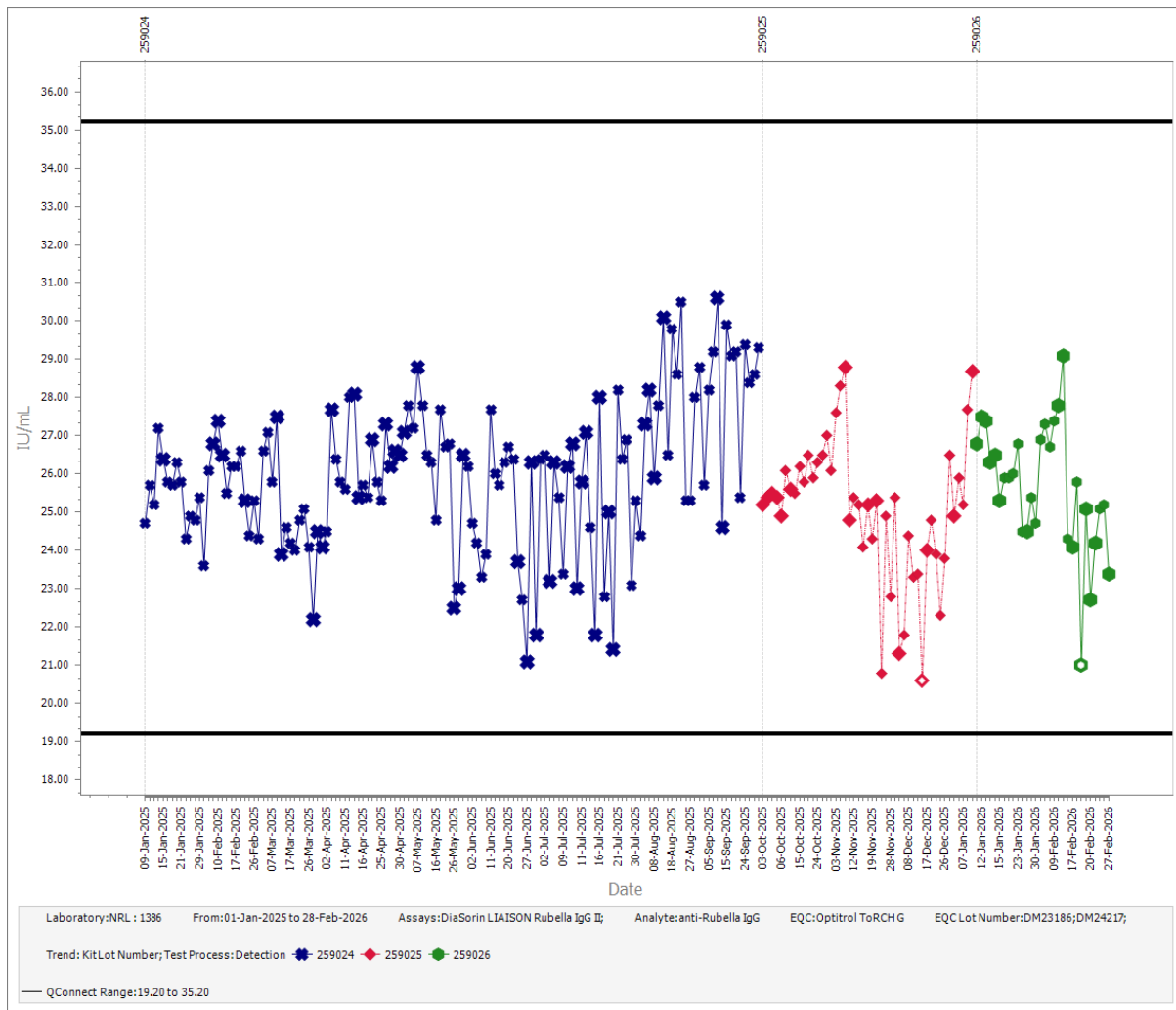


Figure 5: Participant 1386 data reported on the DiaSorin LIAISON Rubella IgG II assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

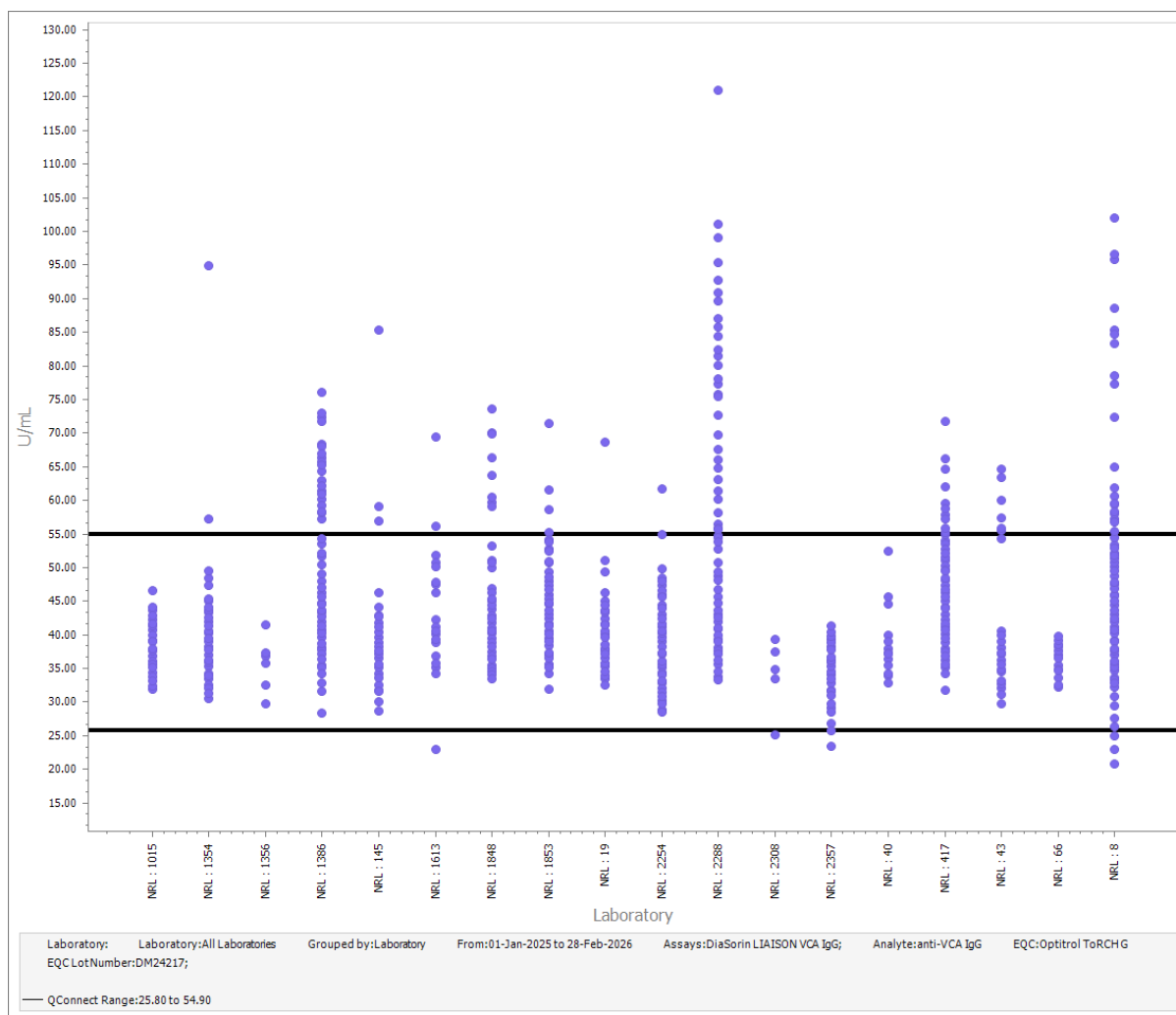


Figure 6: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by participant.

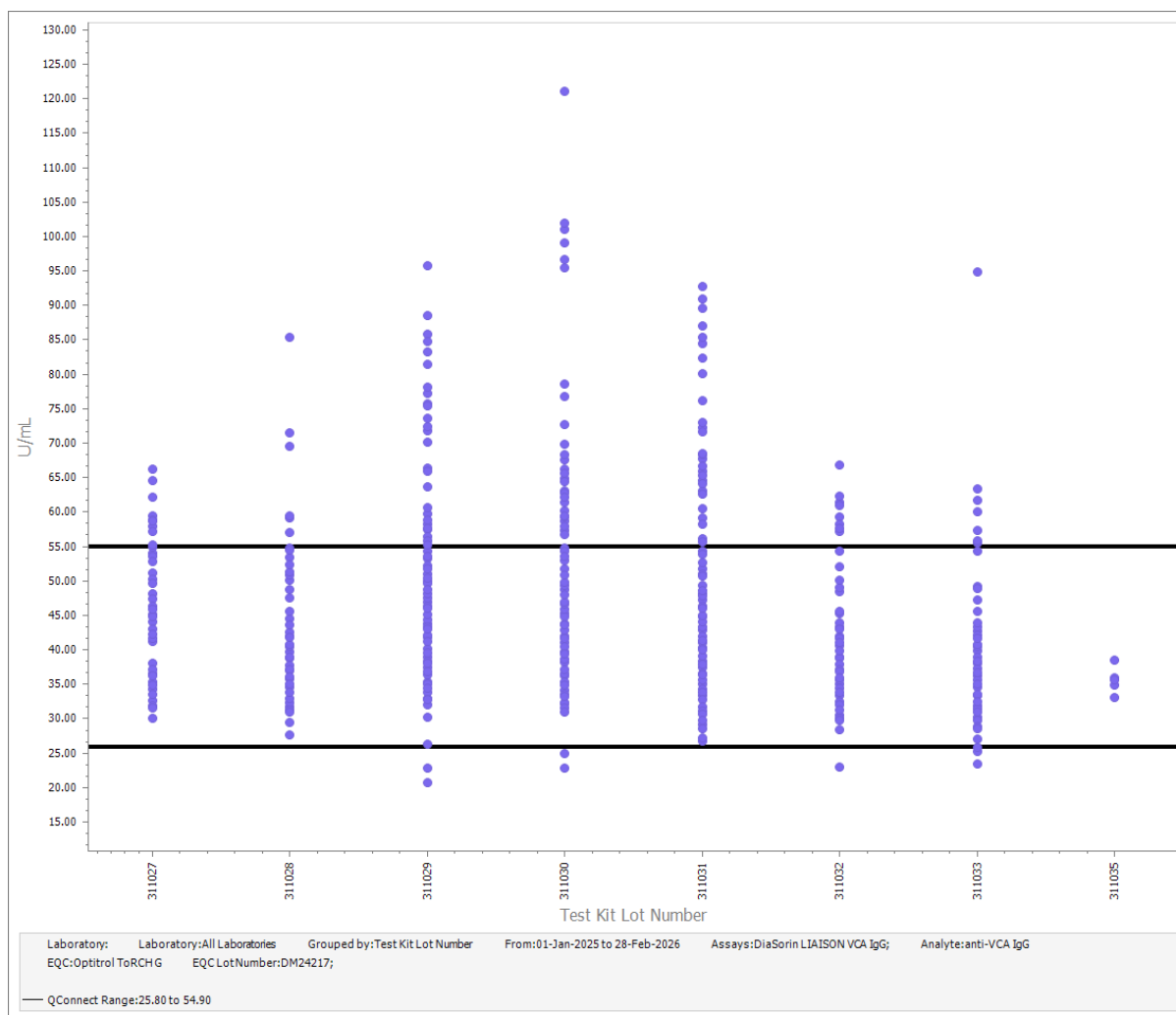


Figure 7: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.

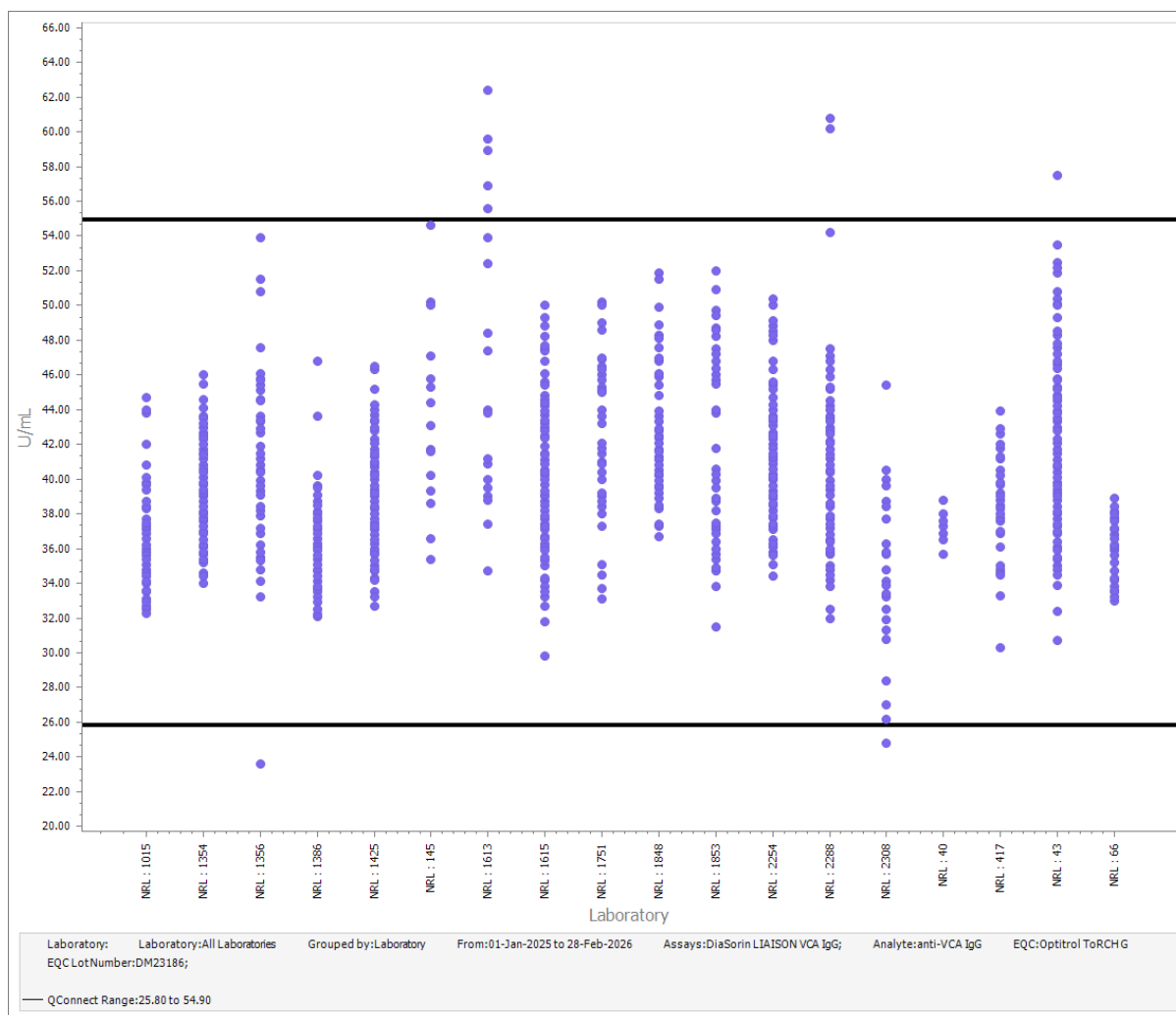


Figure 8: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 by participant.

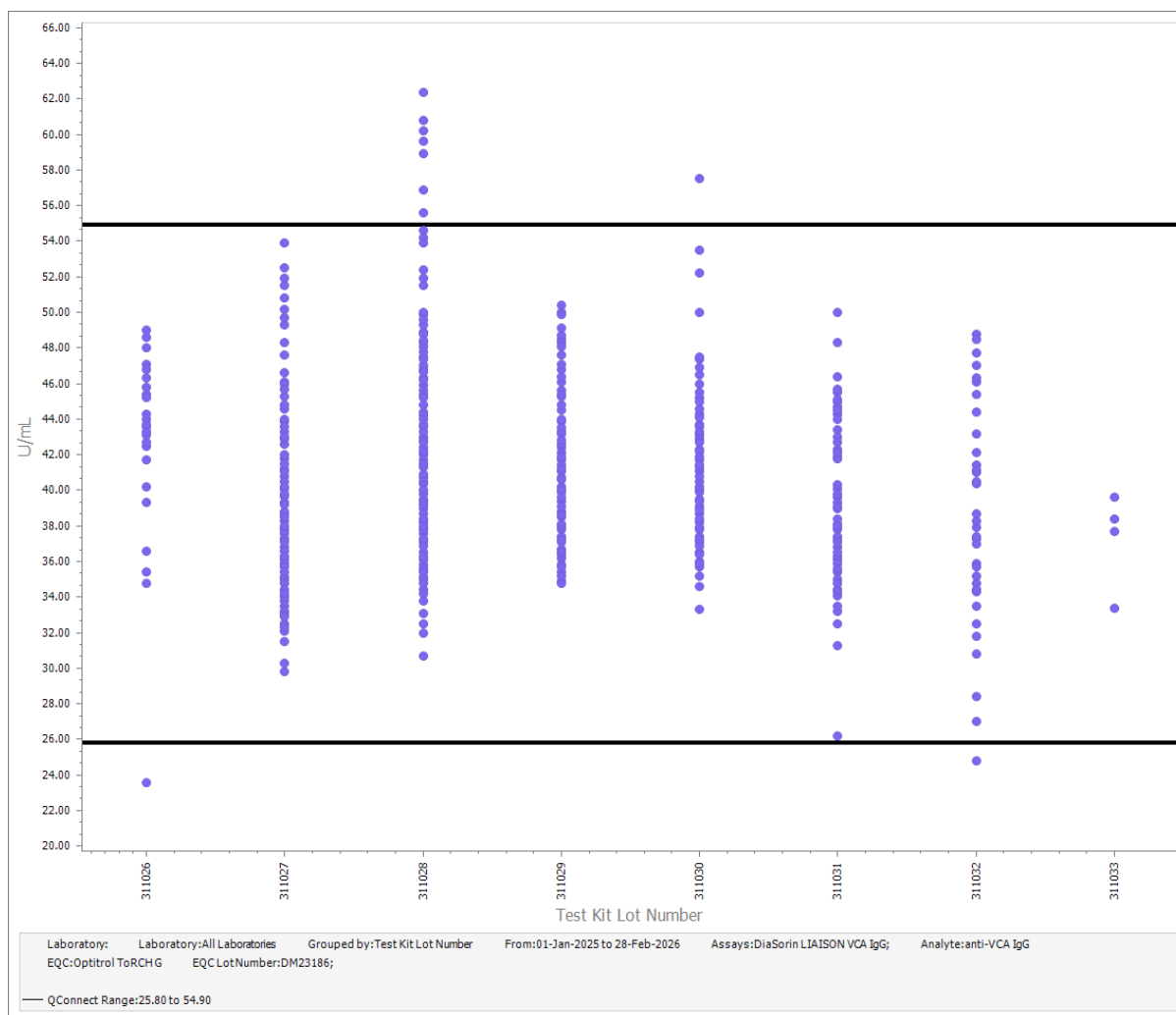


Figure 9: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, by reagent lot.

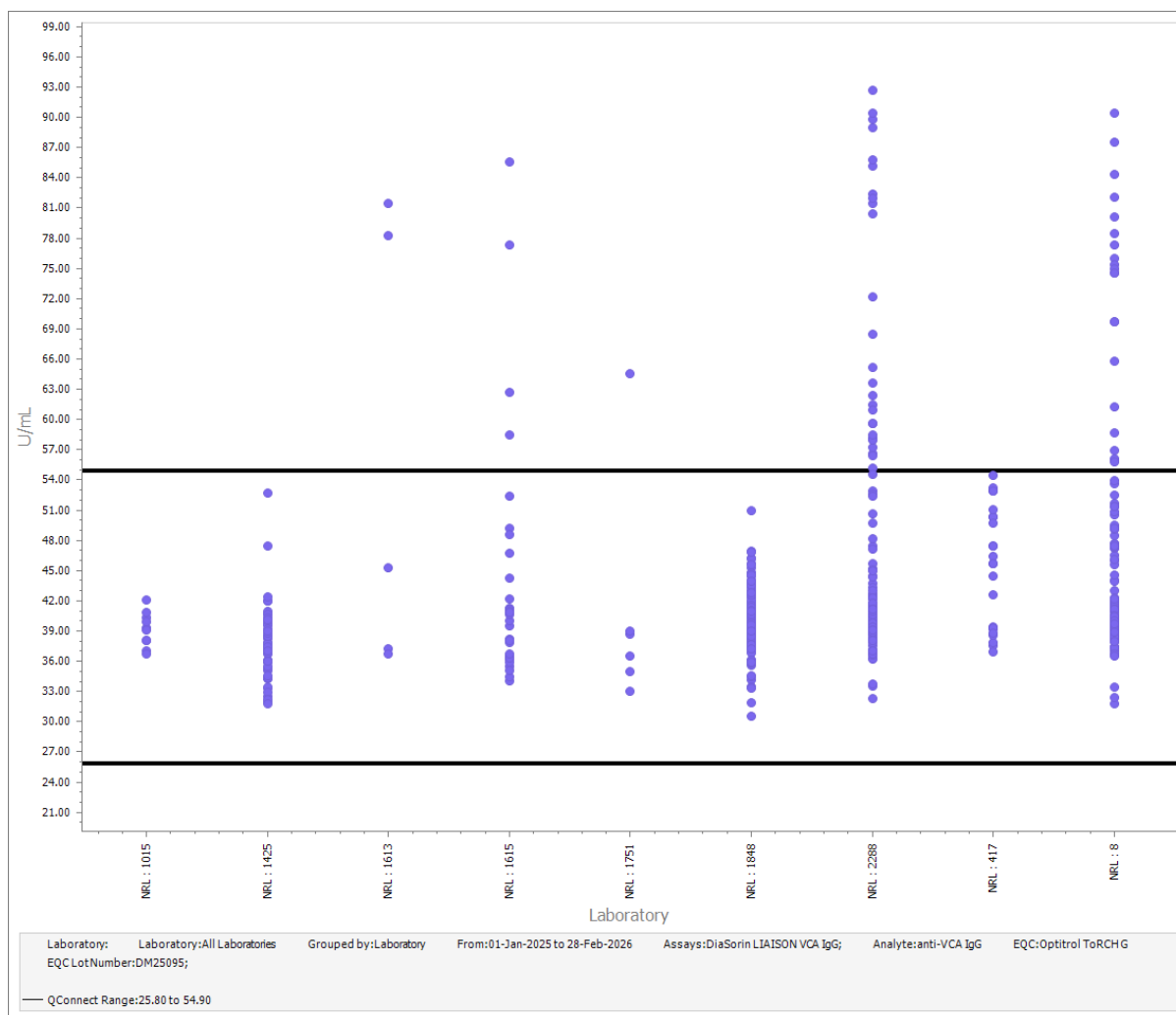


Figure 10: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM25095 by participant.

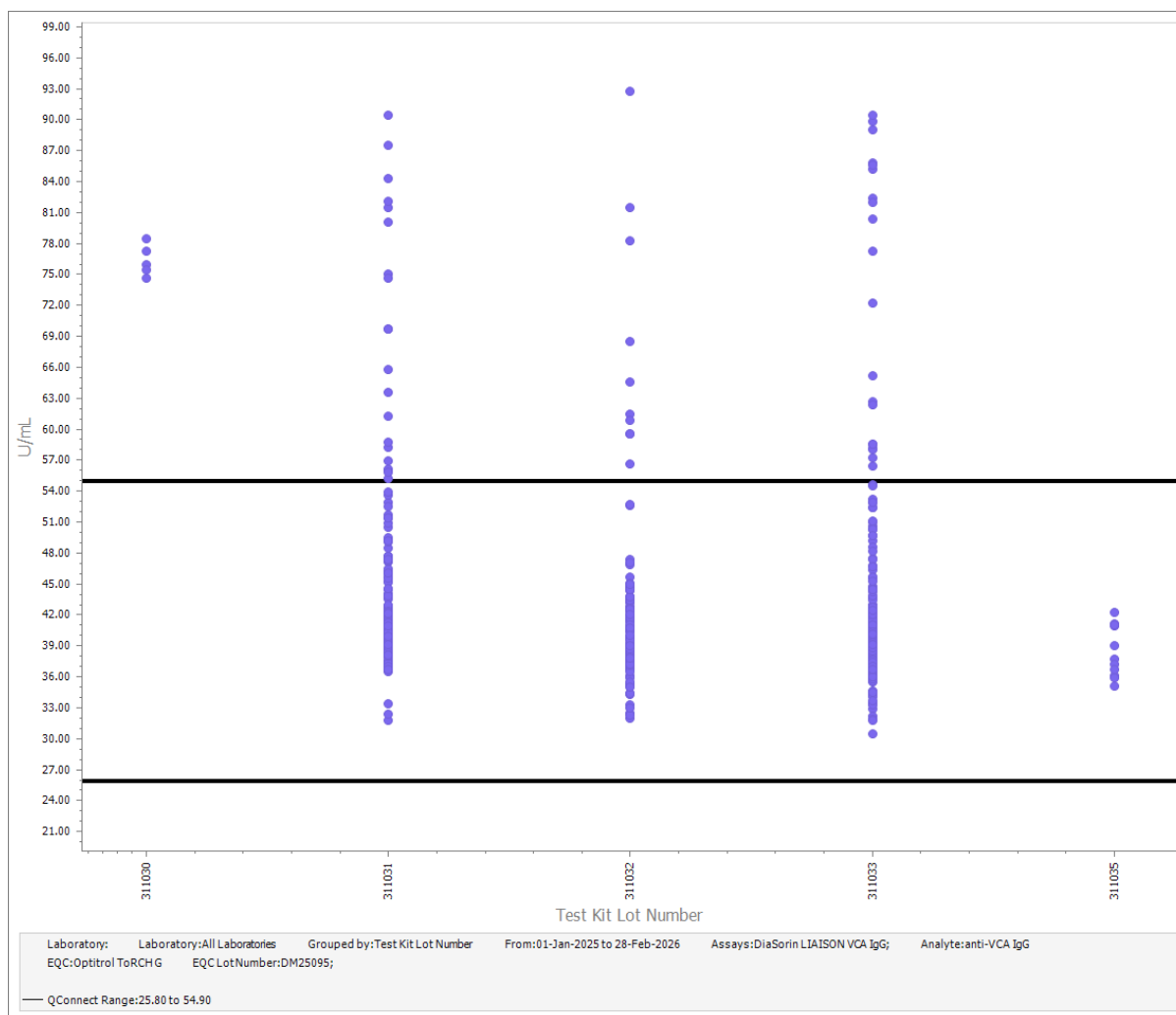


Figure 11: Peer group data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM25095 by reagent lot.

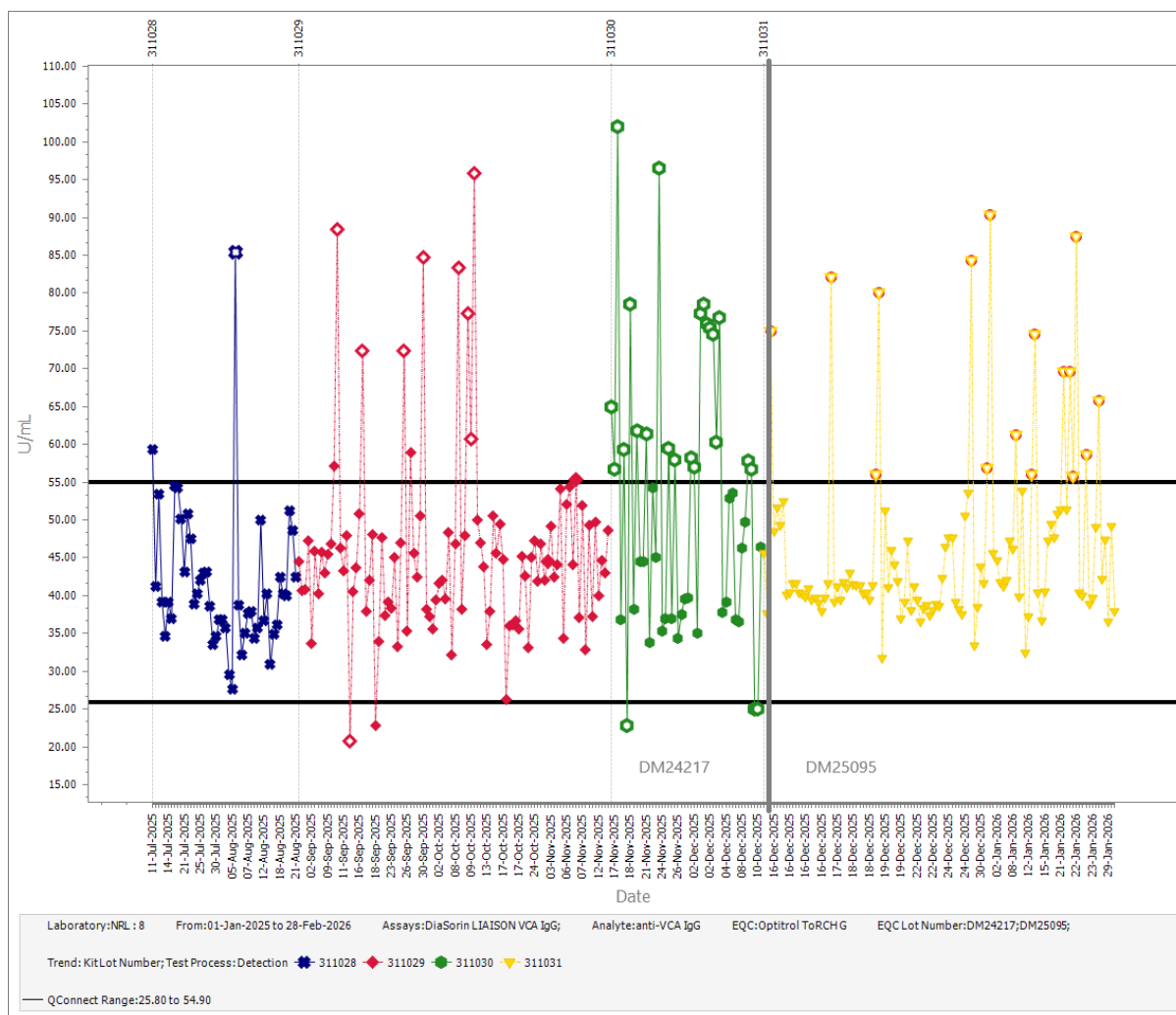


Figure 12: Participant 8 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 and DM25095 by reagent lot.

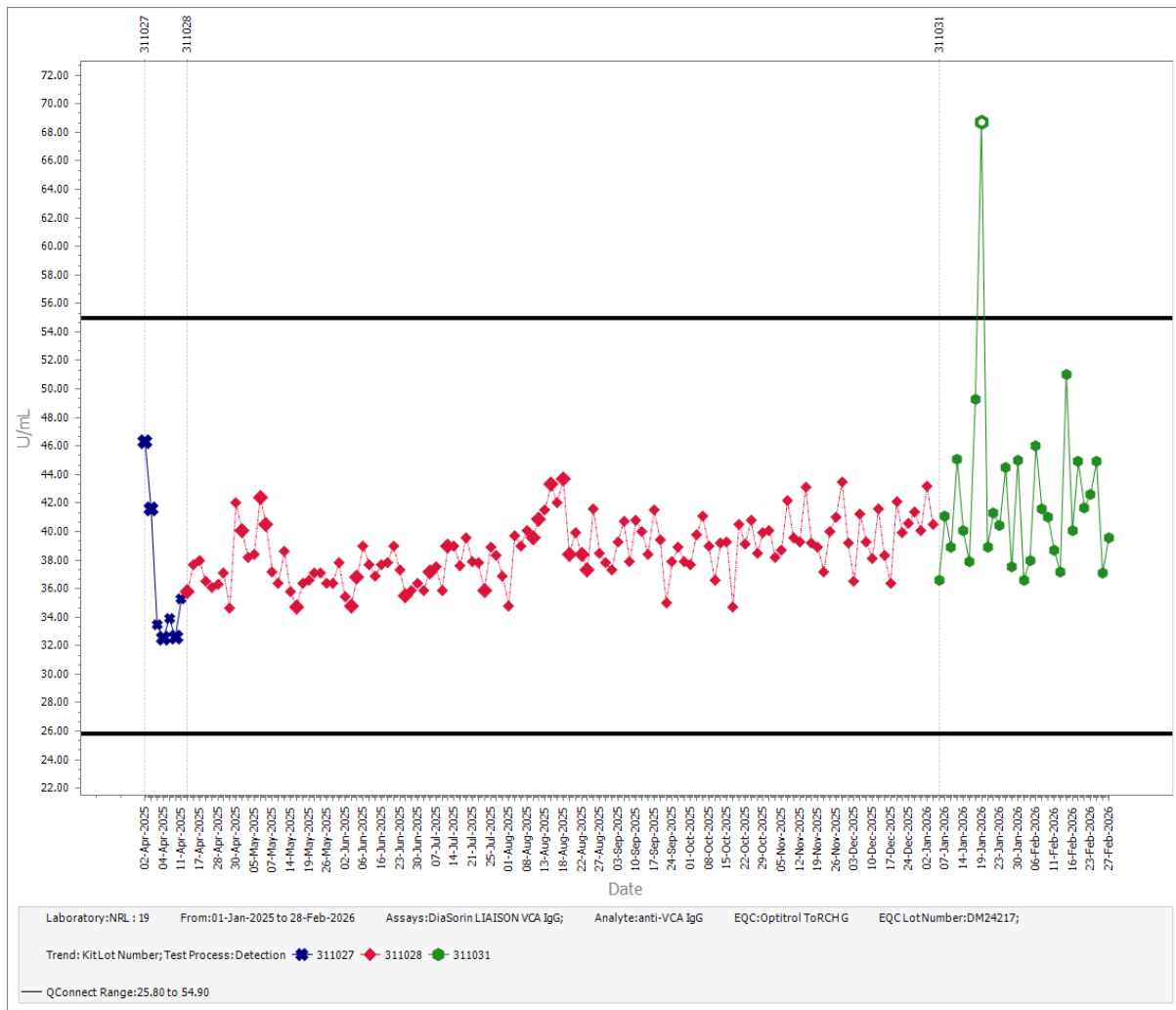


Figure 13: Participant 19 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.

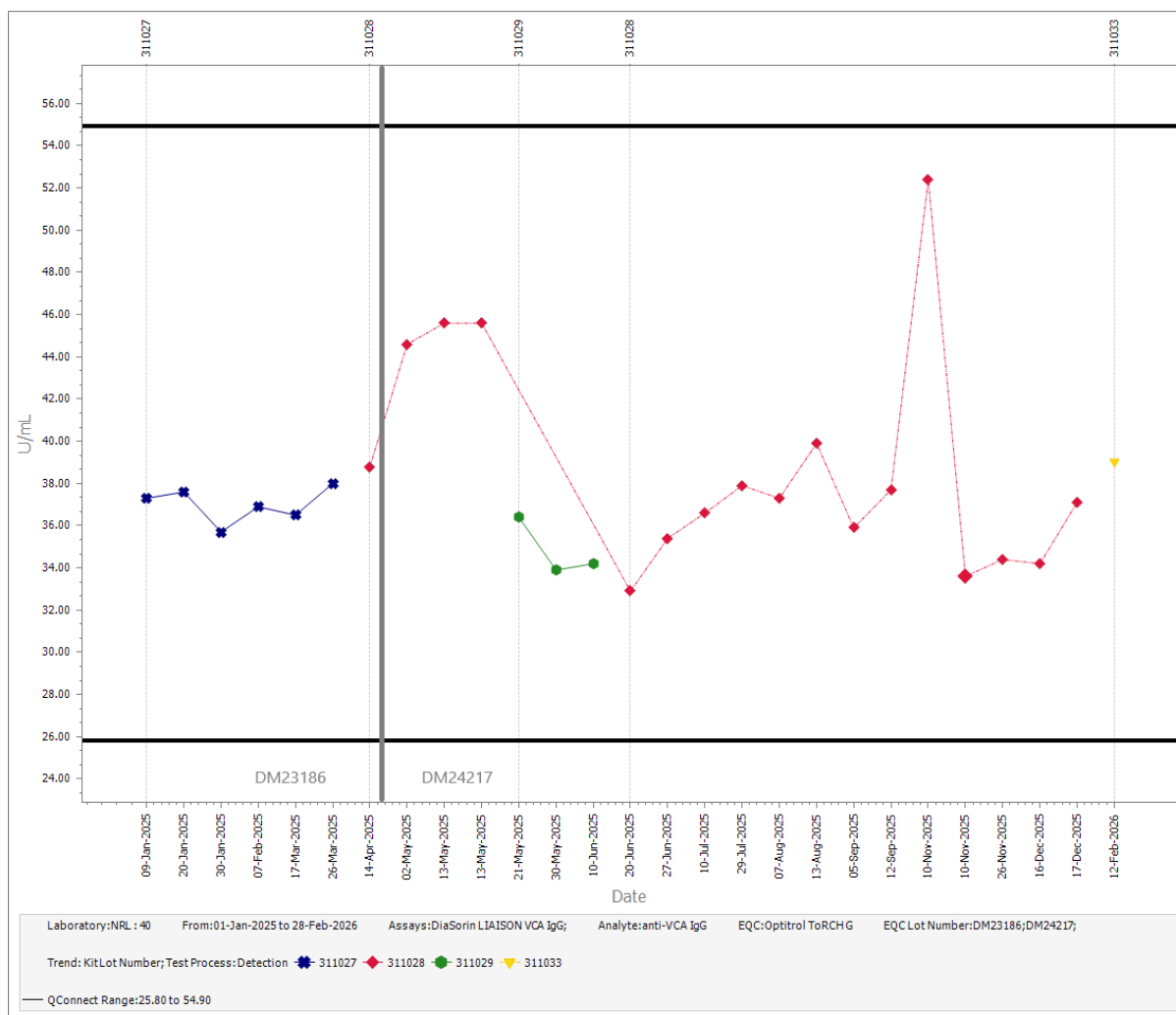


Figure 14: Participant 40 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

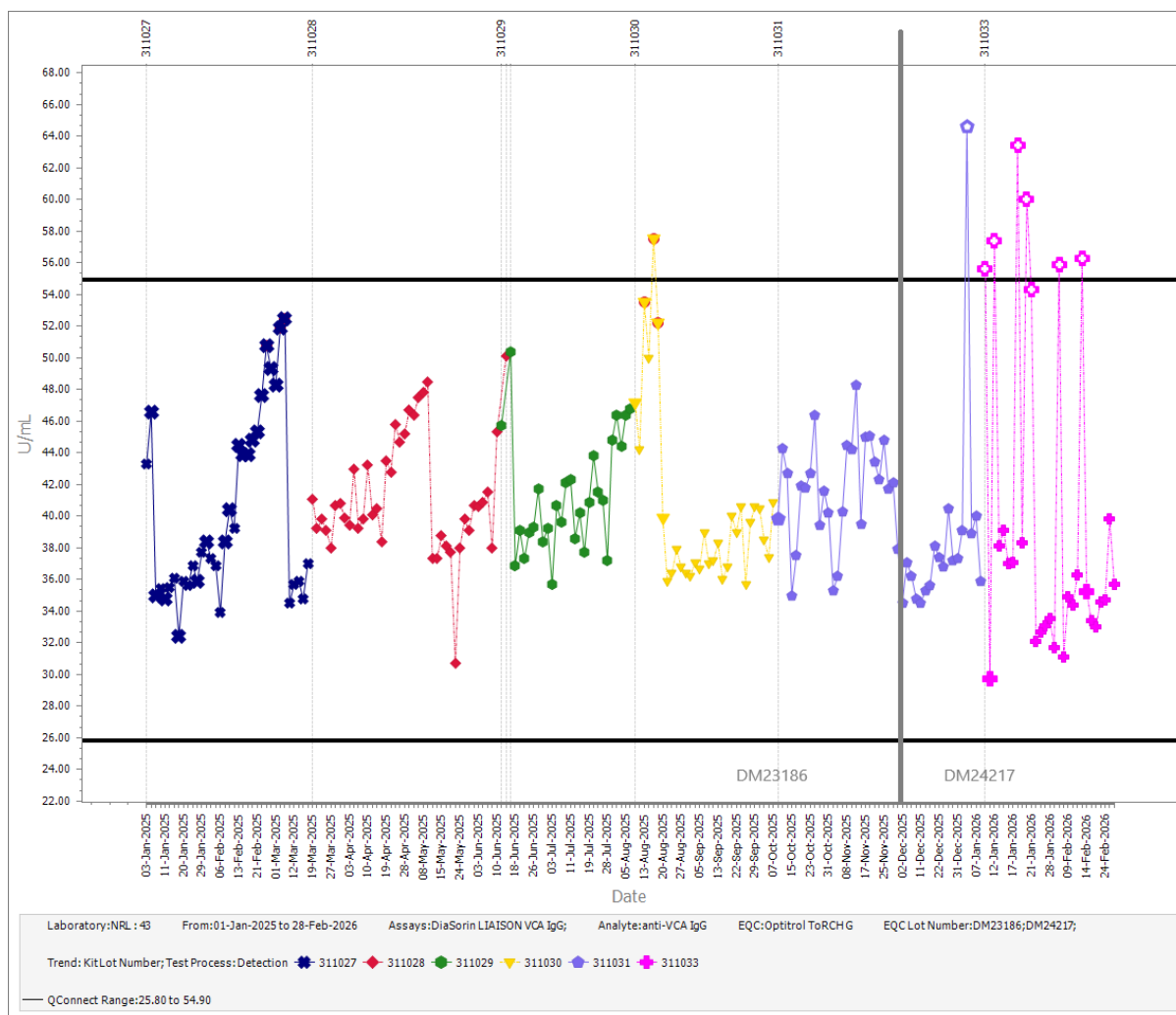


Figure 15 Participant 43 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

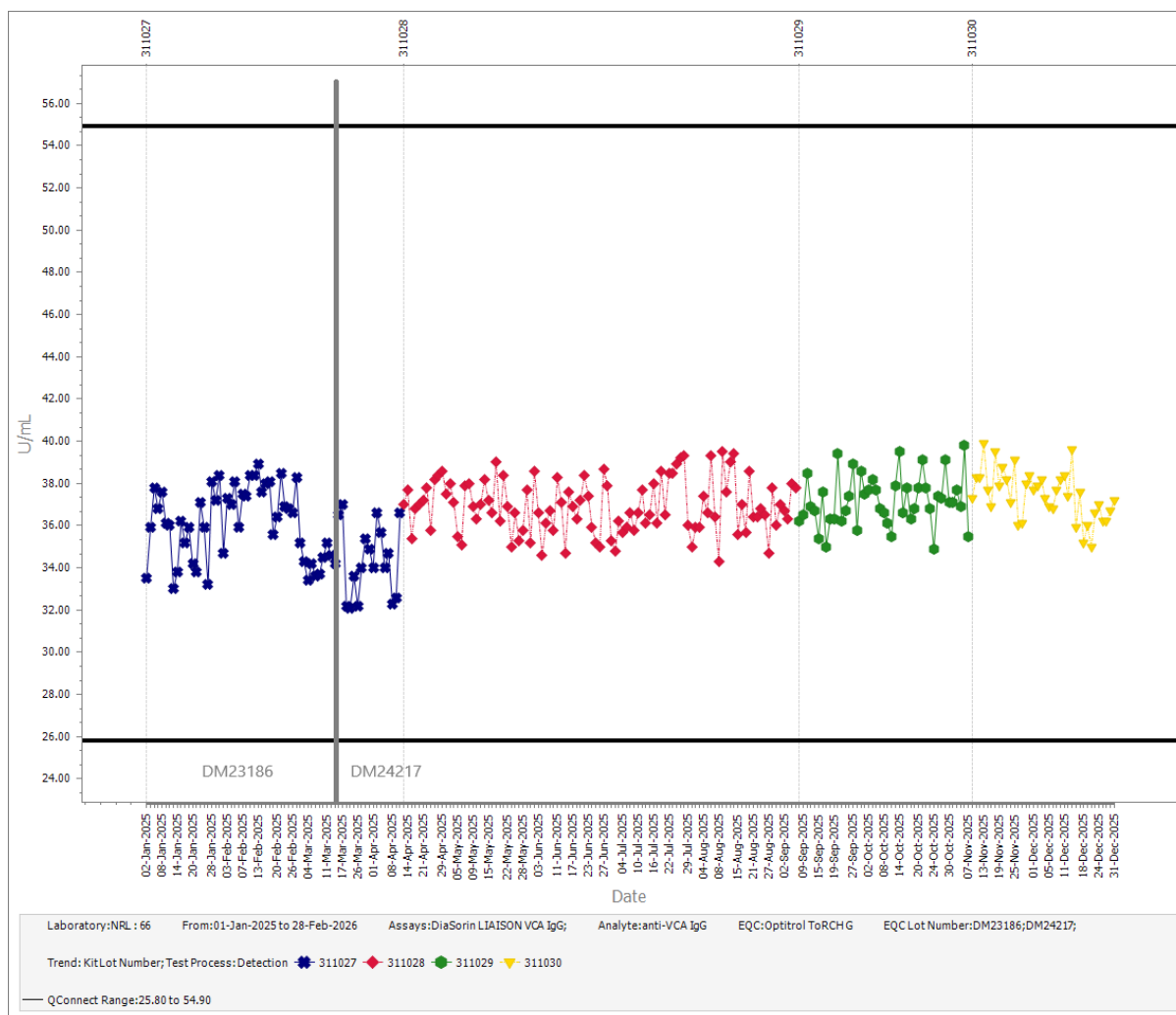
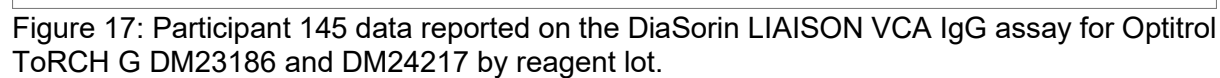


Figure 16: Participant 66 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.



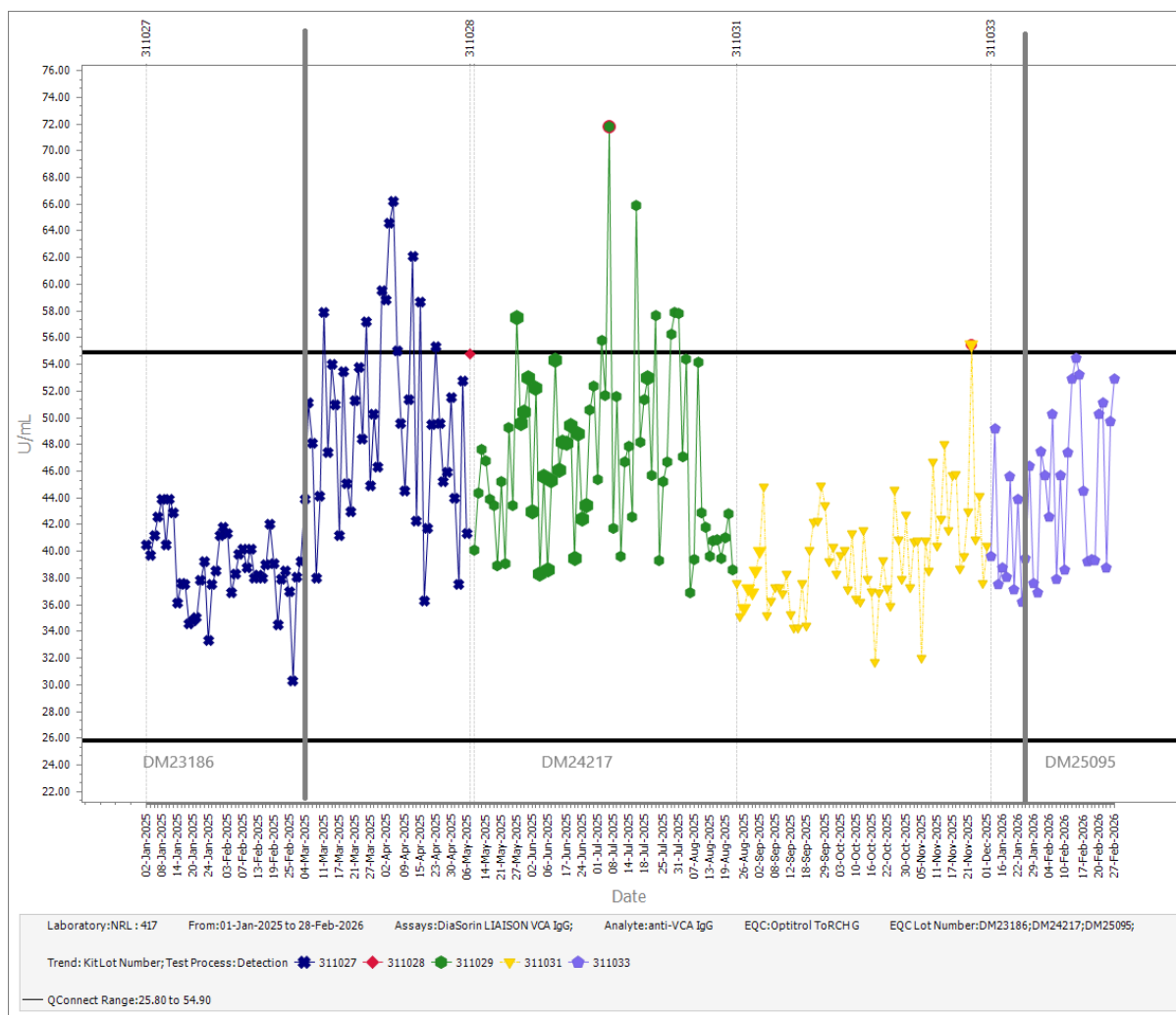


Figure 18: Participant 417 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.

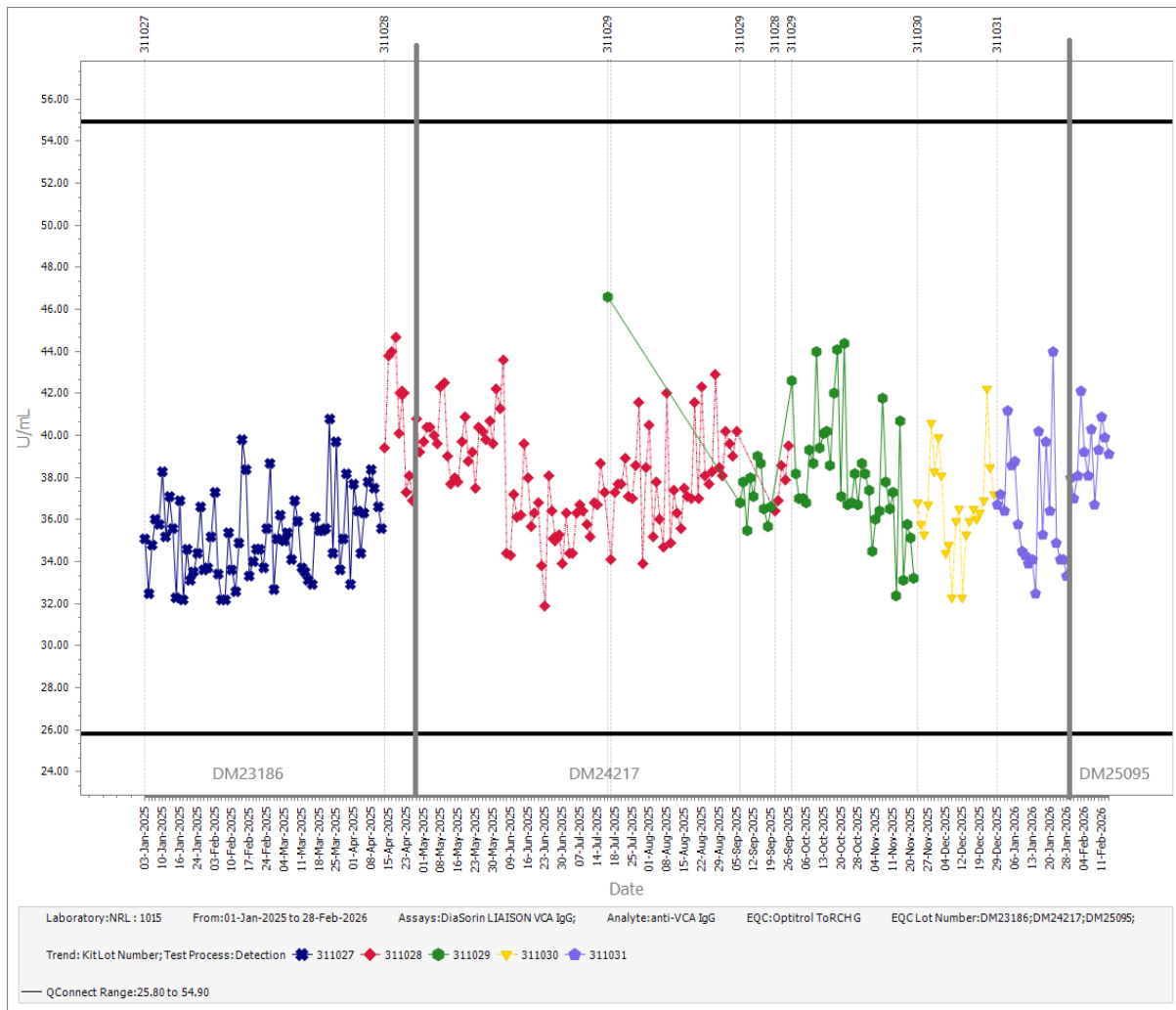


Figure 19: Participant 1015 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.

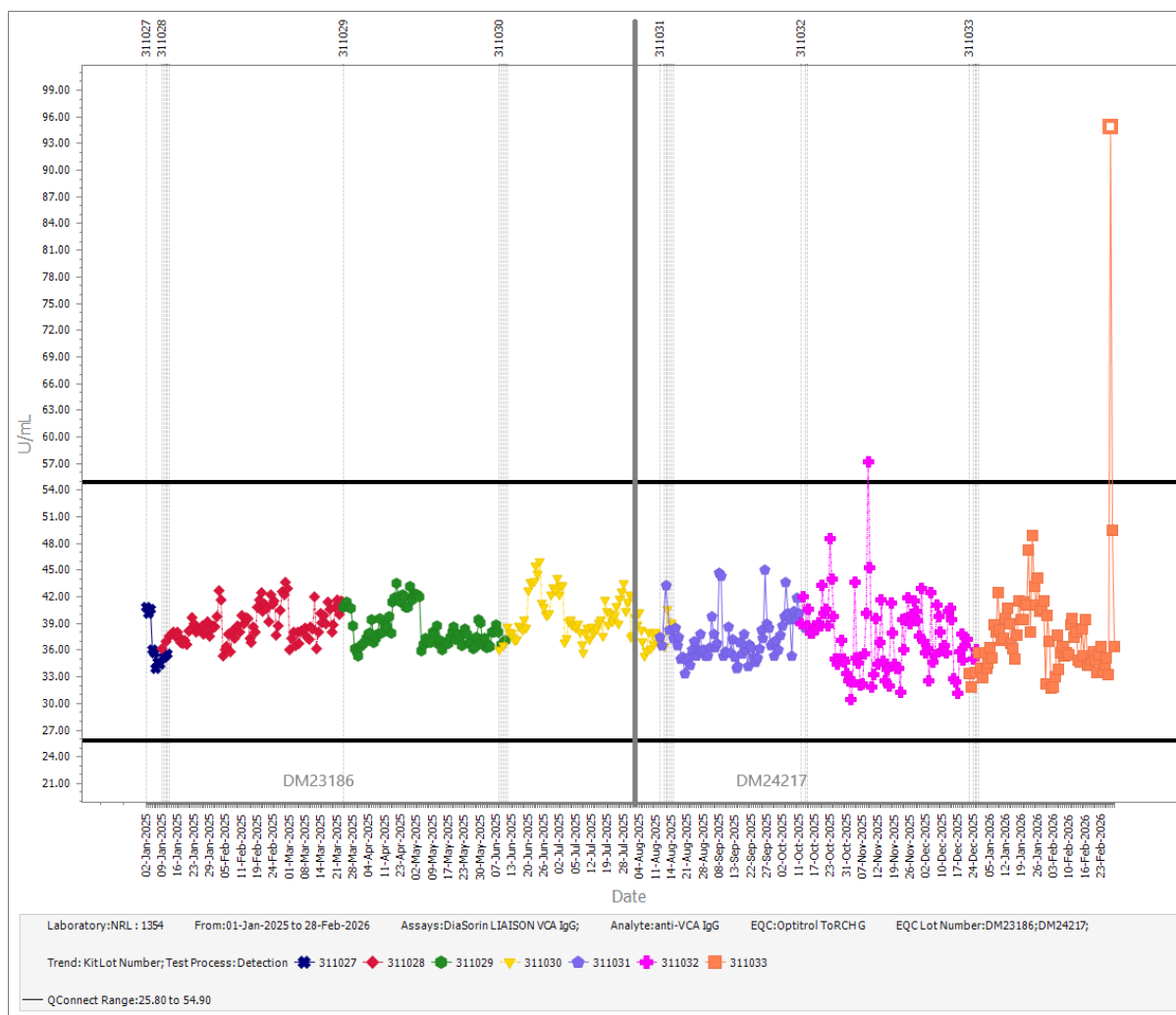


Figure 20: Participant 1354 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

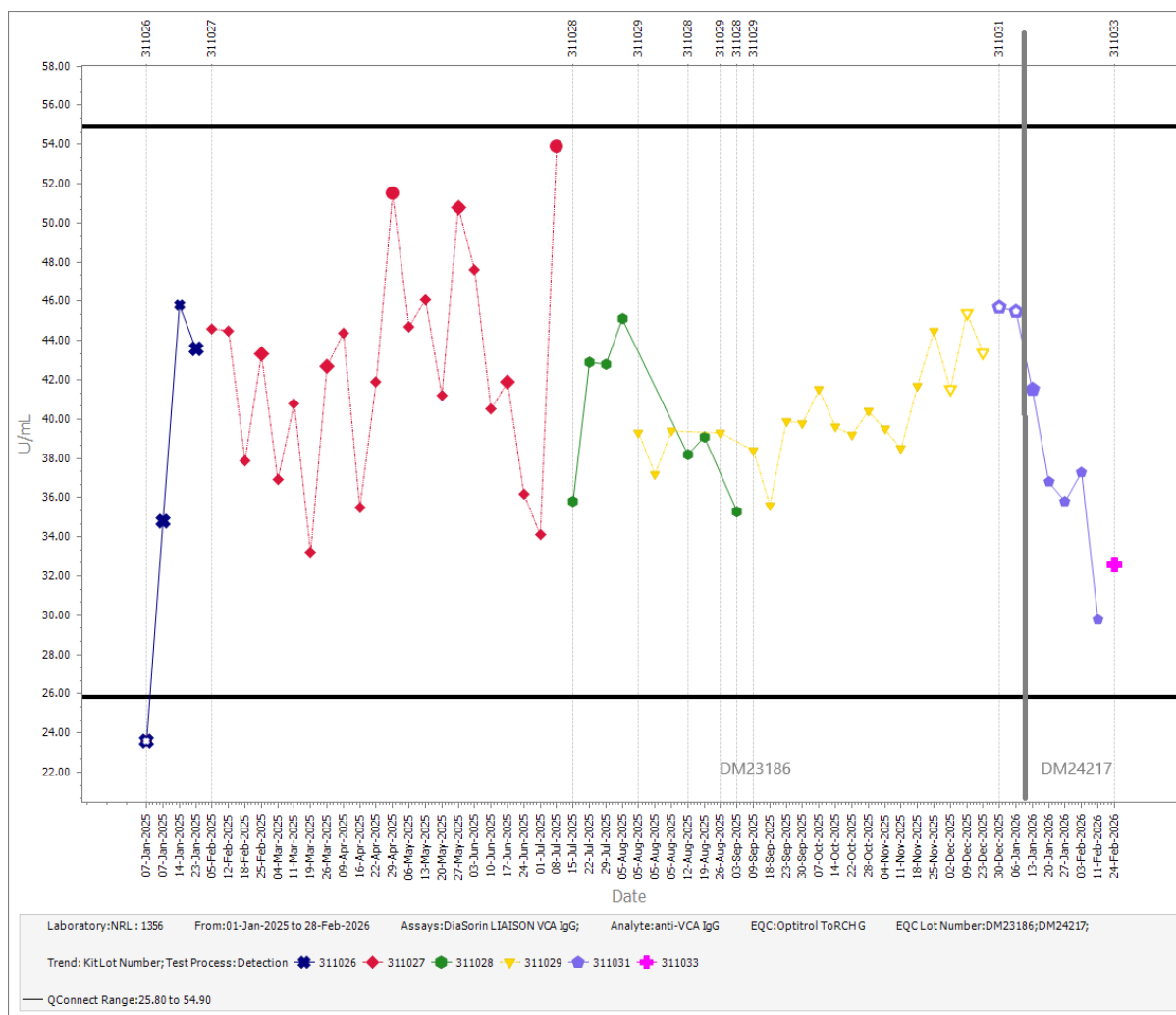


Figure 21: Participant 1356 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

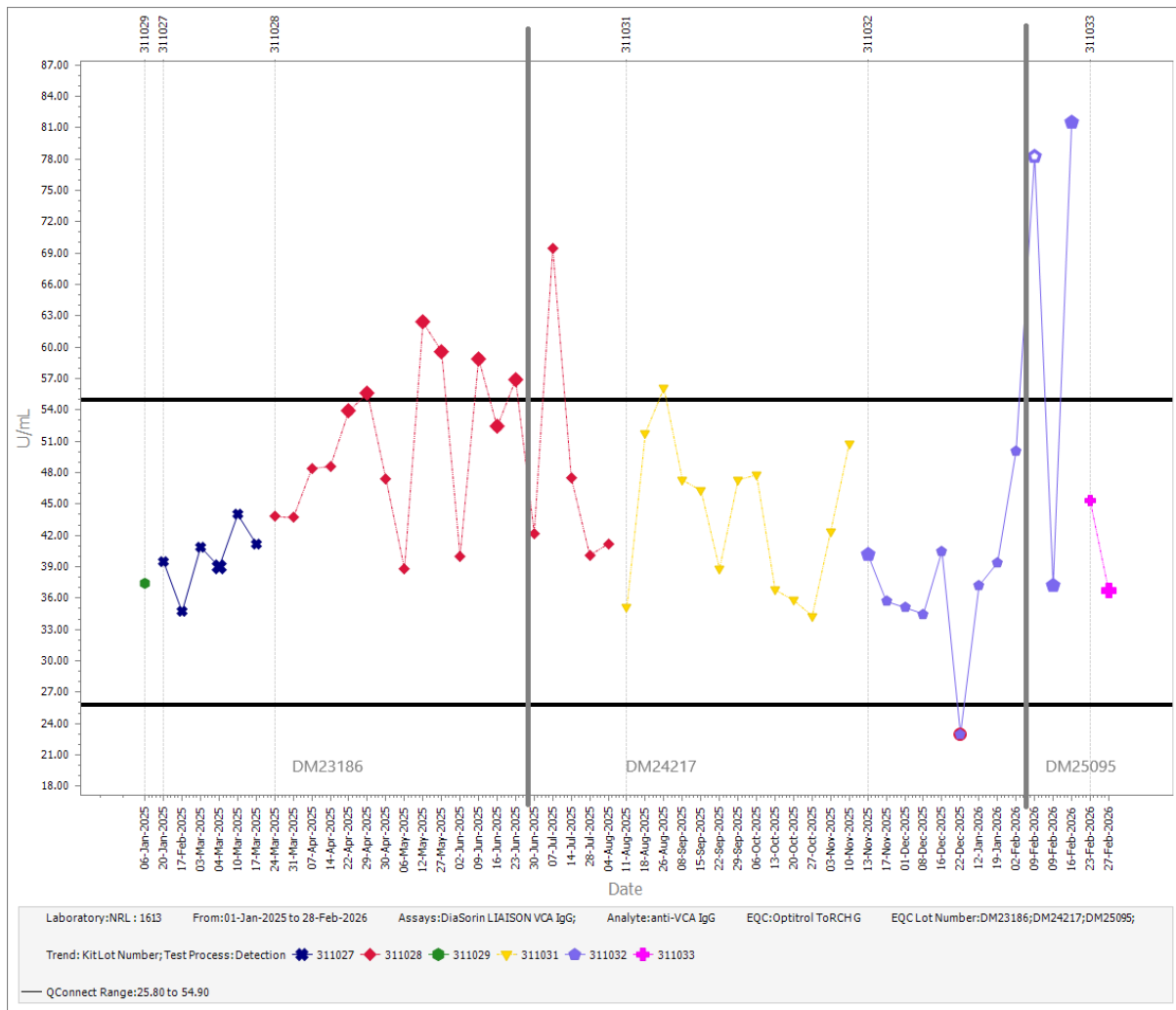


Figure 22: Participant 1613 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.

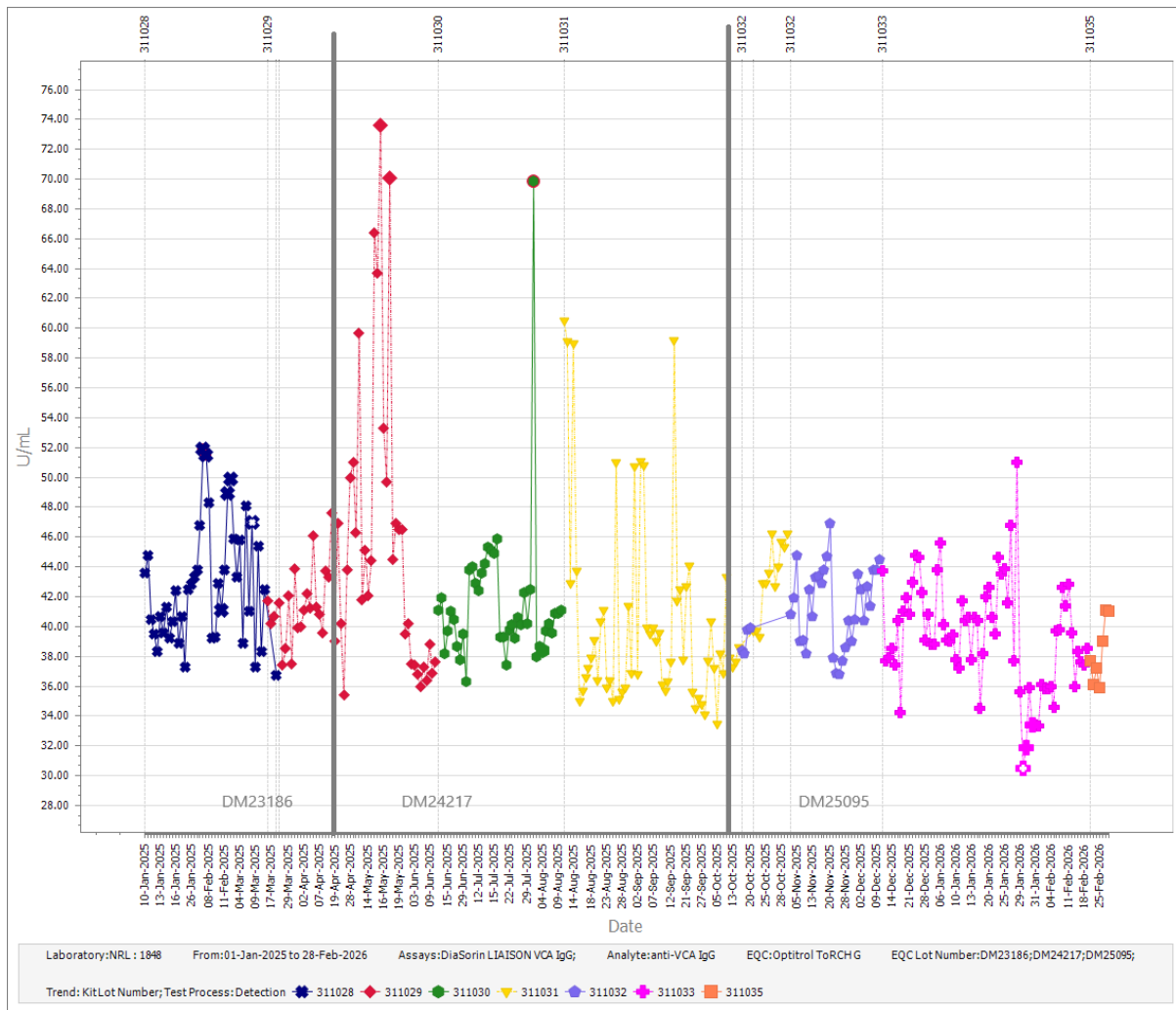


Figure 23: Participant 1848 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.

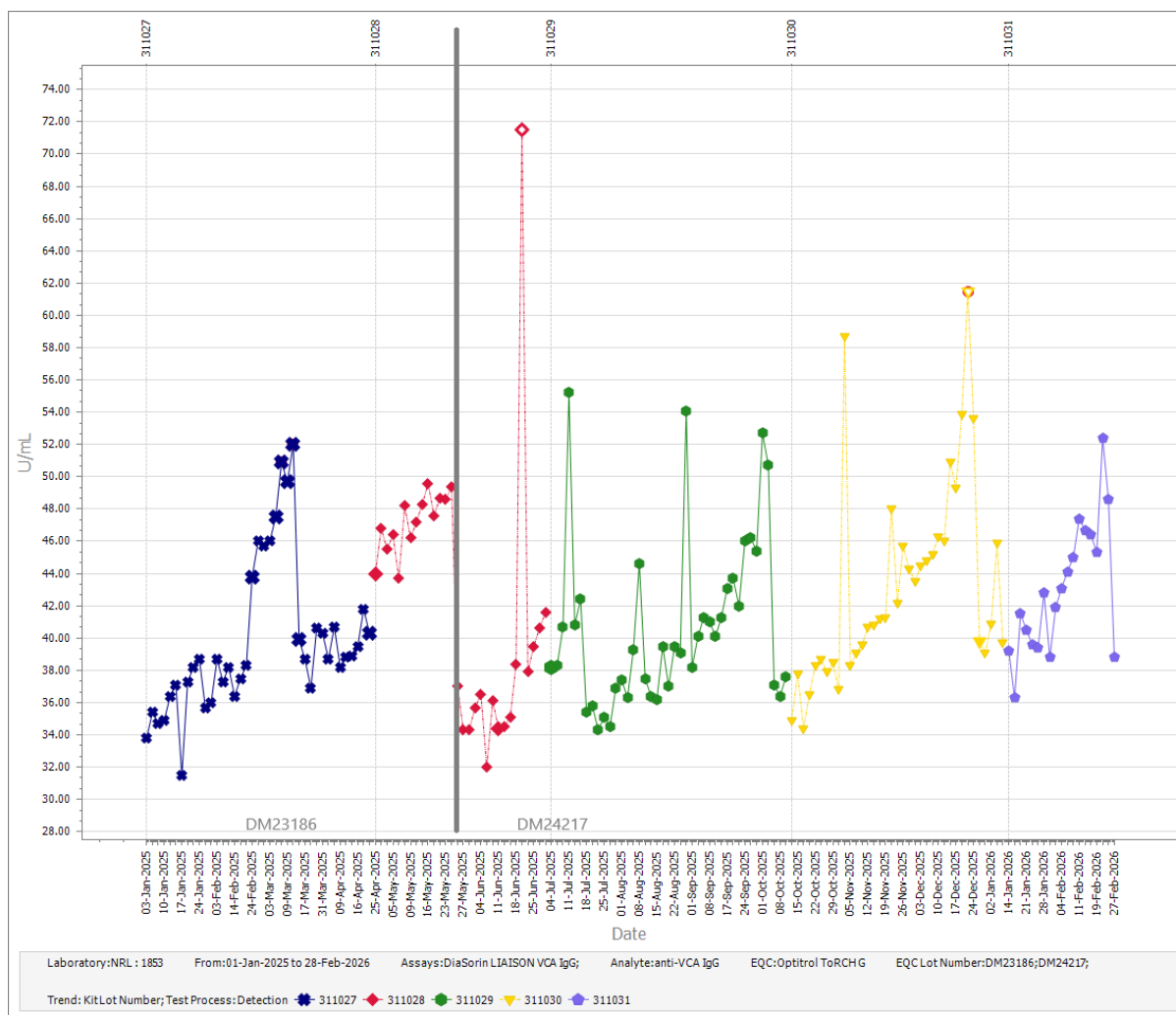


Figure 24: Participant 1853 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

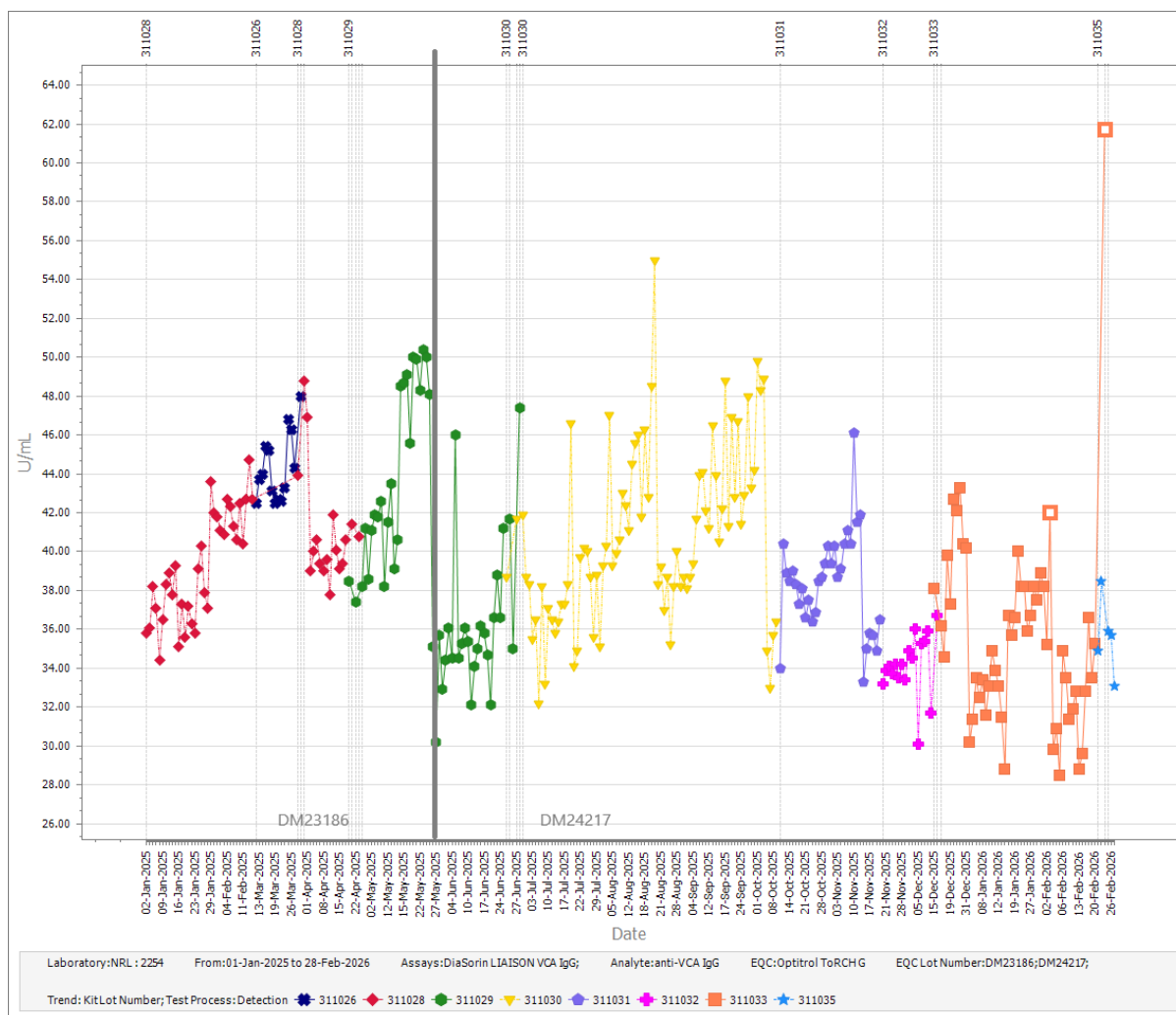


Figure 25: Participant 12254 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

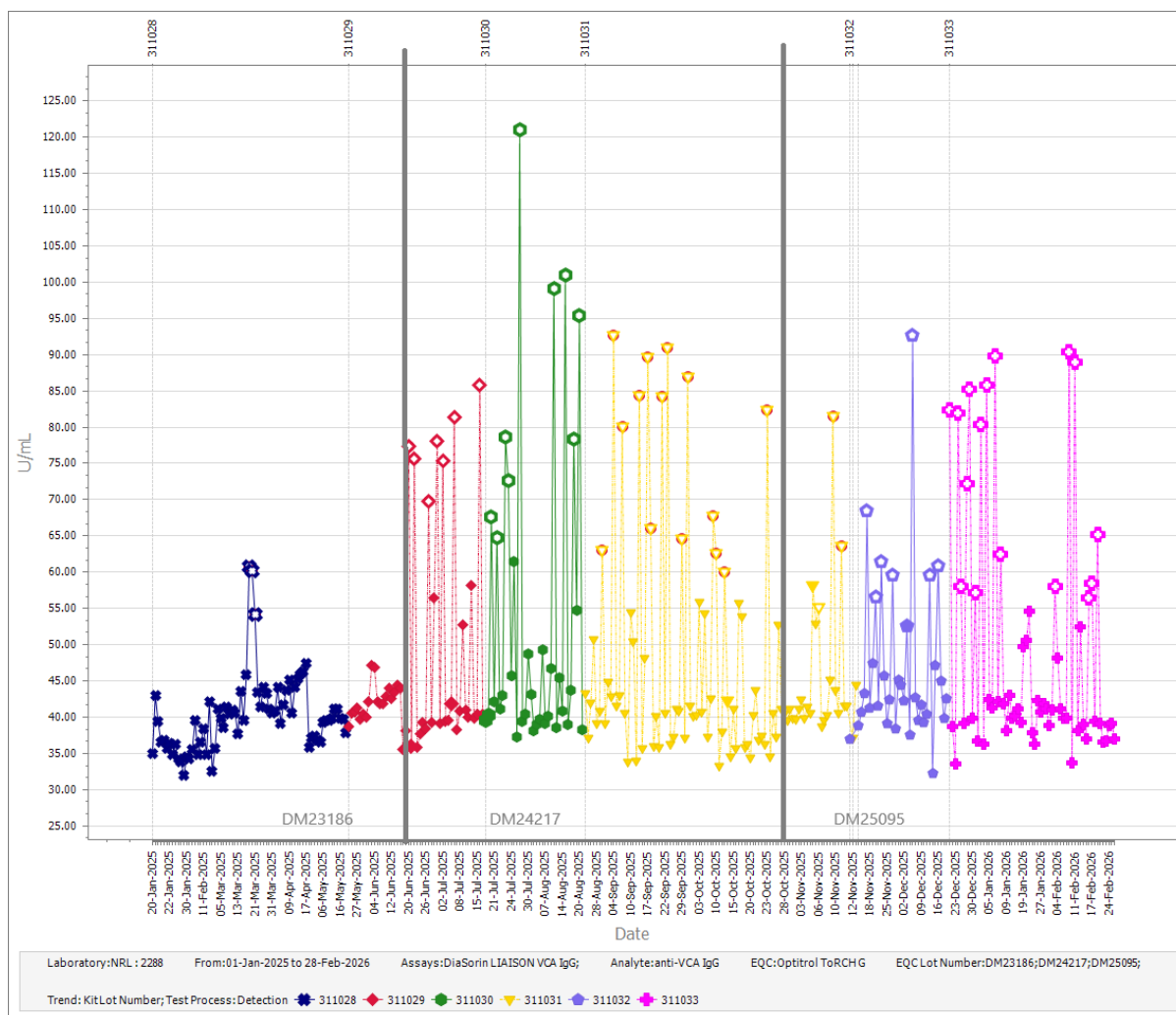


Figure 26: Participant 2288 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186, DM24217 and DM25095 by reagent lot.

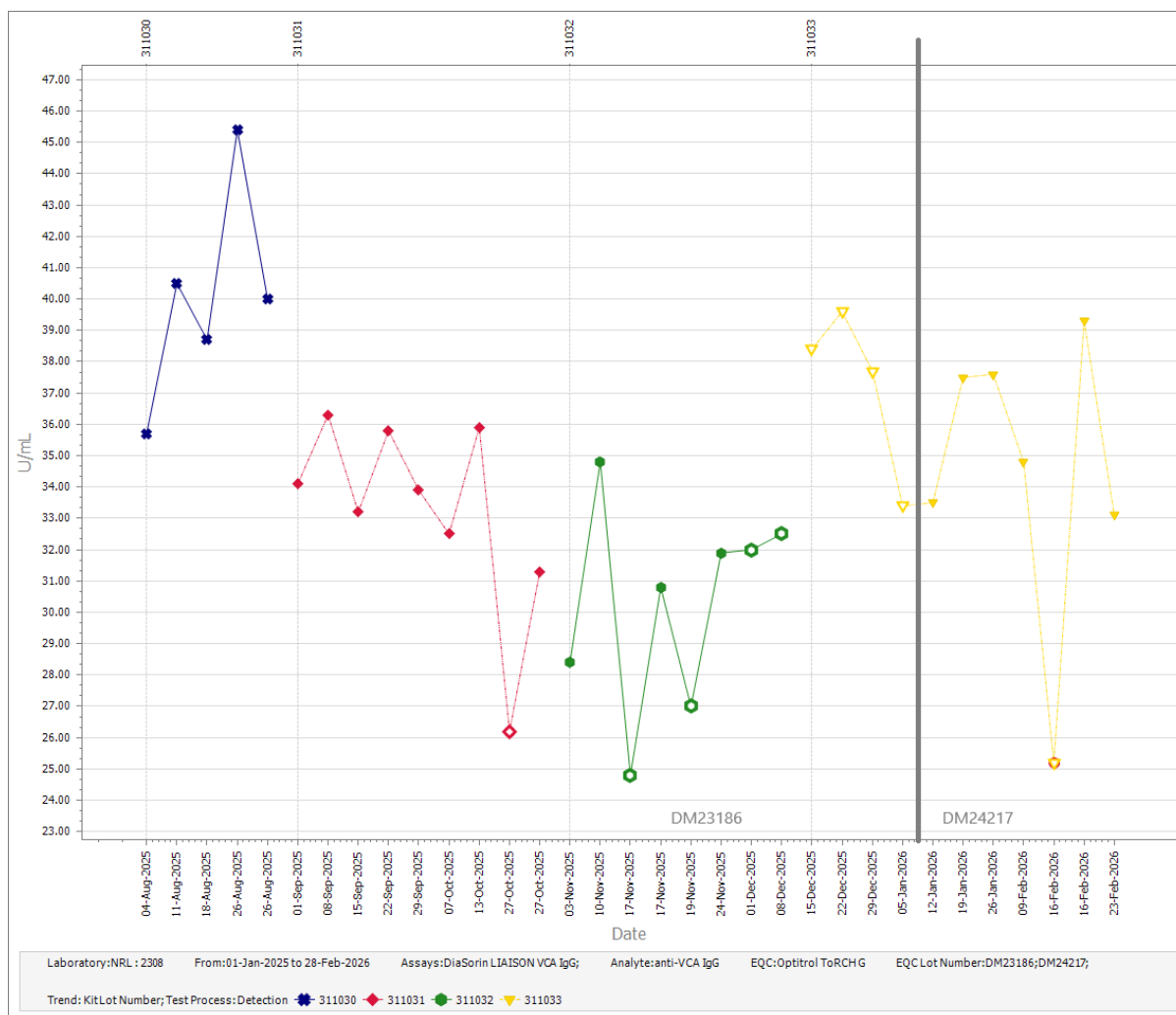


Figure 27: Participant 2288 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM24217 by reagent lot.

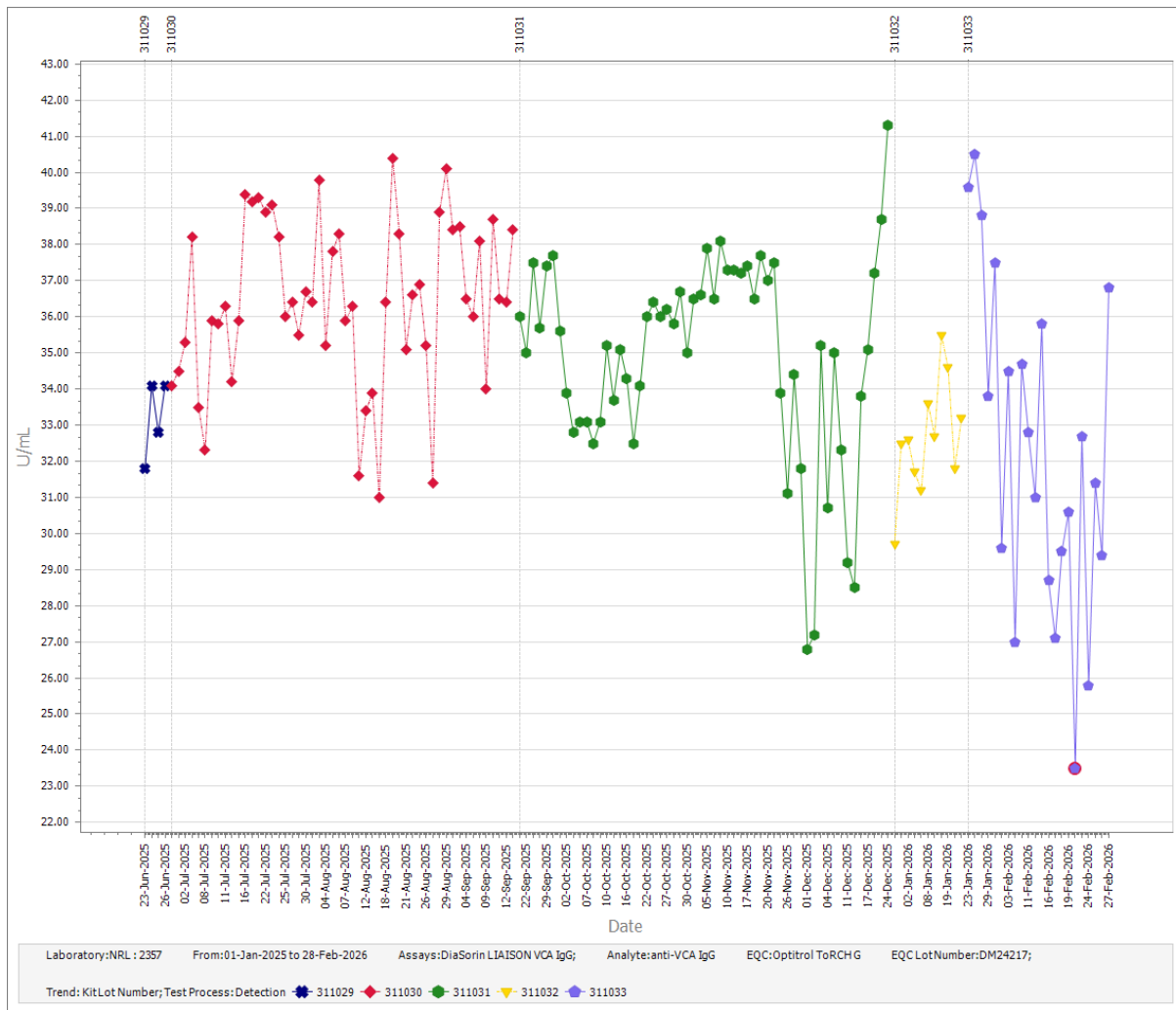


Figure 28: Participant 2357 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM24217 by reagent lot.

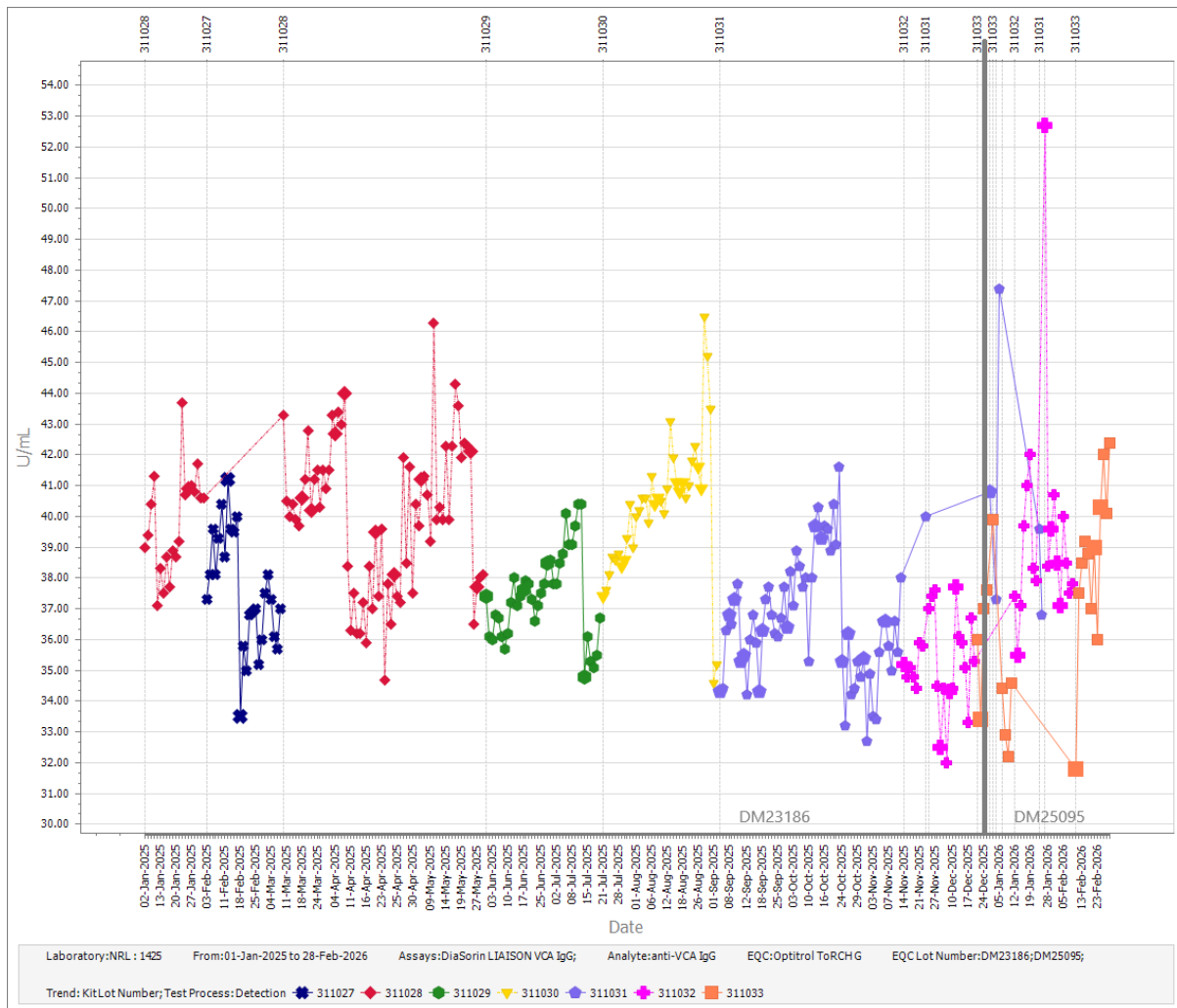


Figure 29: Participant 1425 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.

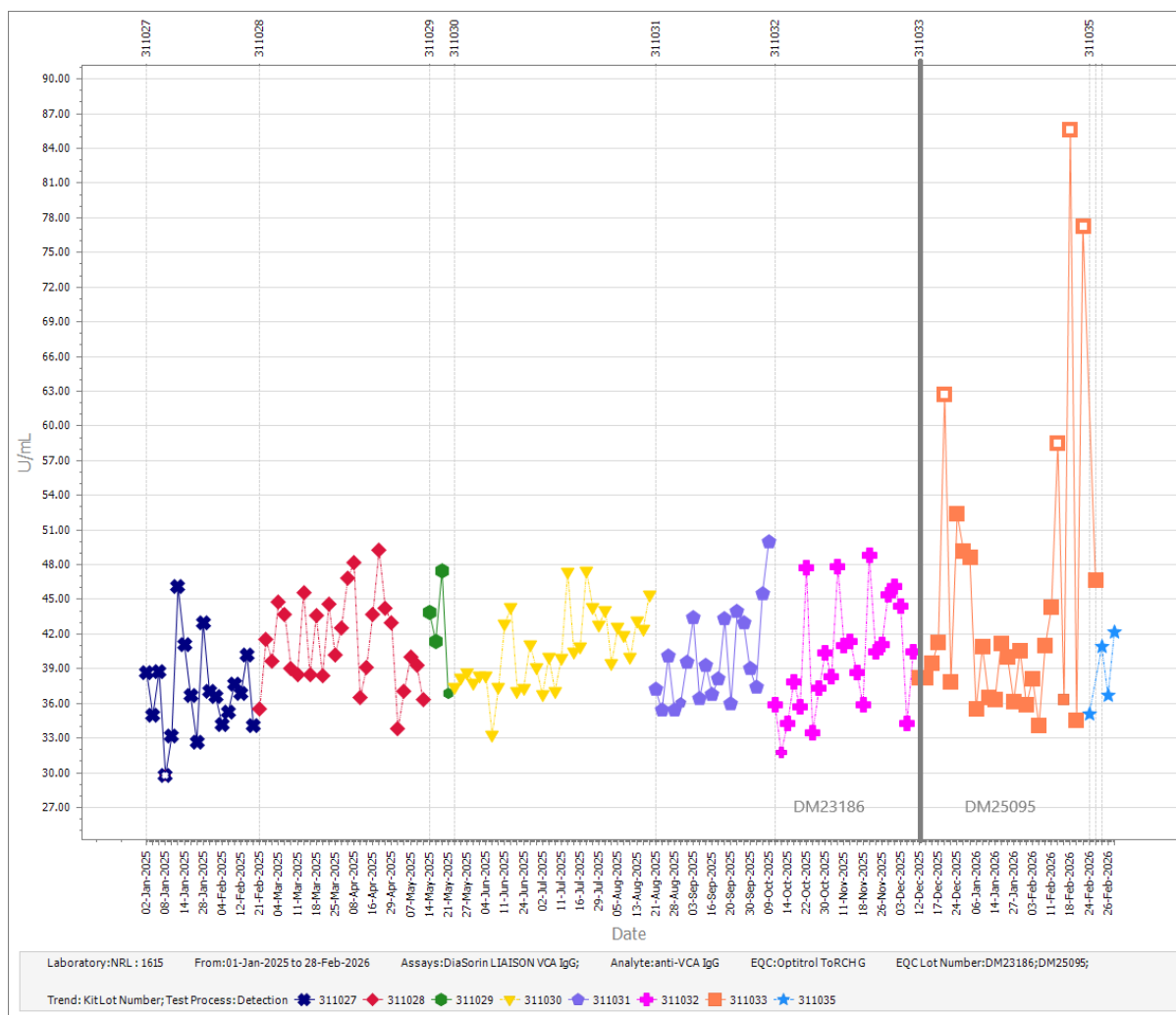


Figure 30: Participant 1615 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.

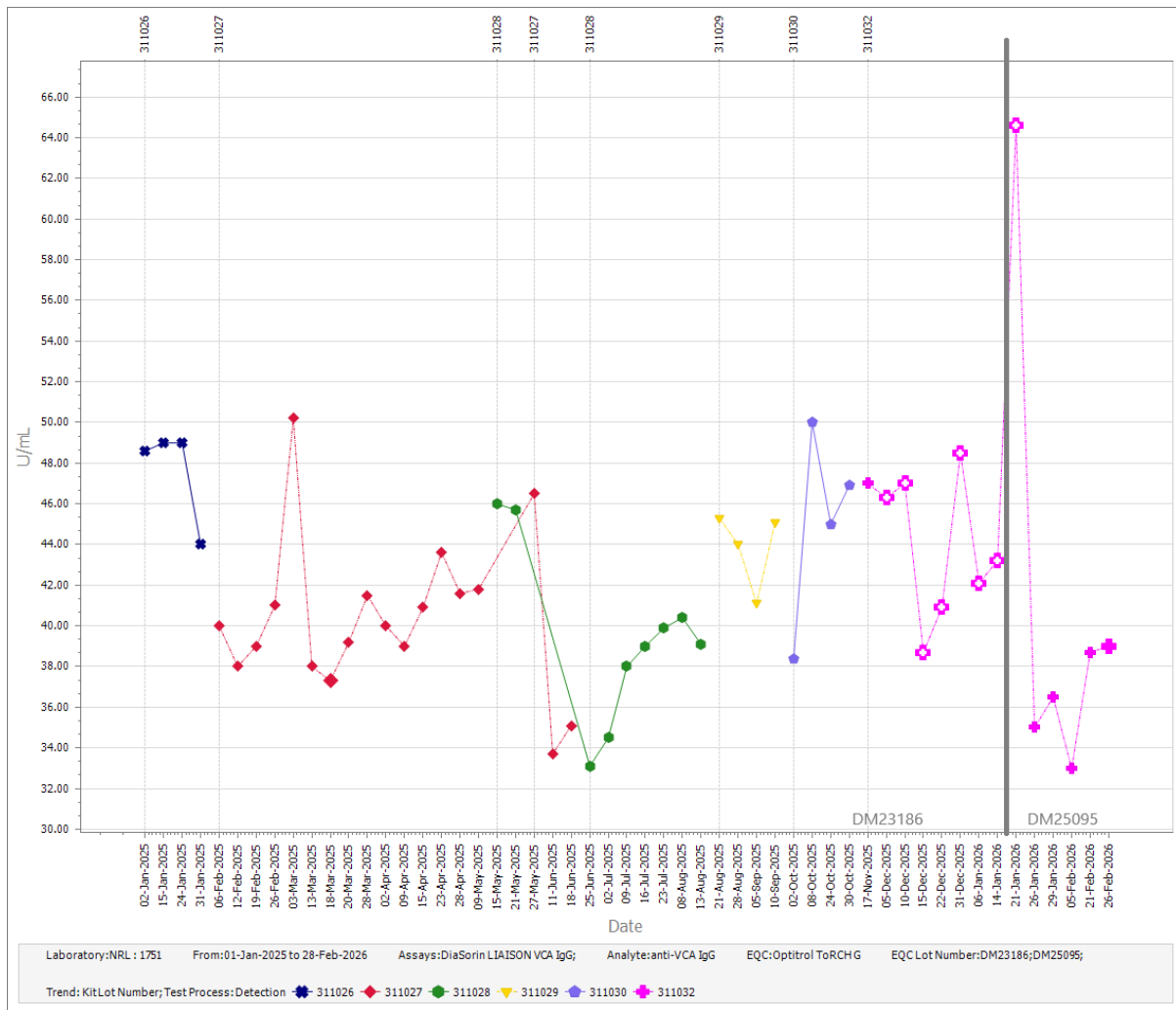


Figure 31: Participant 1751 data reported on the DiaSorin LIAISON VCA IgG assay for Optitrol ToRCH G DM23186 and DM25095 by reagent lot.