

QC SEROLOGY INVESTIGATION PMM-QC-982

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INTRODUCTION

During scheduled monitoring review of QC data submitted to EDCNet for Optitrol ToRCH M QC testing with the DiaSorin LIAISON HSV-1/2 IgM assay, it was observed that all data entered under QC lot DM20144, were entered at the upper limit of the assay, Index Value (IV) 3.50.

This QC / assay combination monitoring was due to a change in the concentration of HSV IgM within Optitrol ToRCH M, which was deliberately lowered in part due to customer feedback and suitability of QC to this assay. The original composition of Optitrol ToRCH M QC lots, where HSV IgM was included at a higher concentration, was designed to be run as a patient sample on the DiaSorin LIAISON HSV-1/2 IgM assay. Patient samples undergo a dilution step that assay control samples do not. Other Optitrol QC products are run as Controls on the DiaSorin LIAISON platform, which caused some laboratory workflow errors resulting in invalid data in EDCNet, as other assays do not require any dilution steps.

Planned additional monitoring was to ensure laboratories had noted the change and were following the updated QC IFU.

FINDINGS

- Figure 1 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 2 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by participant.
- Figure 3 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 and DM20144 by participant.
- Figure 4 – Participant 18 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.
- Figure 5 – Participant 1304 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.
- Figure 6 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.
- Figure 7 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by reagent lot.
- Figure 8 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 and DM20144 by reagent lot.
- Figure 9 – Participant 1026 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by reagent lot.
- Figure 10 – Peer group data for DiaSorin LIAISON CMV IgM II, Optitrol ToRCH M DM20144 by participant.
- Figure 11 – Peer group data for DiaSorin LIAISON EBV IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 12 – Peer group data for DiaSorin LIAISON Rubella IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 13 – Peer group data for Abbott Alinity i CMV IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 14 – Peer group data for Abbott Alinity i EBV VCA IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 15 – Peer group data for Abbott Alinity i Rubella IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 16 – Peer group data for Abbott Alinity i Toxo IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 17 – Peer group data for Abbott ARCHITECT CMV IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 18 – Peer group data for Abbott ARCHITECT EBV VCA IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 19 – Peer group data for Abbott ARCHITECT Rubella IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 20 – Peer group data for Abbott ARCHITECT Toxo IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 21 – Peer group data for Ortho VITROS CMV IgM, Optitrol ToRCH M DM20144 by participant.

- Figure 22 – Peer group data for Ortho VITROS Rubella IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 23 – Peer group data for Ortho VITROS Toxoplasma IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 24 – Peer group data for Roche Elecsys Rubella IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 25 – Peer group data for Roche Elecsys Toxo IgM, Optitrol ToRCH M DM20144 by participant.
- Figure 26 – Peer group data for Siemens ATELLICA IM Rubella IgM (Rub M), Optitrol ToRCH M DM20144 by participant.
- Figure 27 – Peer group data for Siemens Novagност EBV-VCA IgM, Optitrol ToRCH M DM20144 by participant.

DISCUSSION

When investigating data reported for Optitrol ToRCH M DM20144 testing with the DiaSorin LIAISON HSV-1/2 IgM assay, data from all participants in the peer group and assays where Optitrol ToRCH M DM20144 was in use were investigated to establish whether there was any evidence of trends or patterns across the peer group or other assays and testing platforms.

Figure 1 shows peer group data for Optitrol ToRCH M DM20144 testing with the DiaSorin LIAISON HSV-1/2 IgM assay. All three participants reported all data at IV 3.50 showing no variation in data.

Figure 2 shows peer group data for Optitrol ToRCH M DM19030 testing with the DiaSorin LIAISON HSV-1/2 IgM assay. Two participants reported data below IV 3.50 and showed expected variation and spread, reporting data between IV 1.72 – 3.50.

Figure 3 shows peer group data for Optitrol ToRCH M DM19030 and DM20144, testing with the DiaSorin LIAISON HSV-1/2 IgM assay, illustrating the differences in data spread between the QC lots.

Figure 4 shows Participant 18 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot showing consistent data entry at IV 3.50 across all reagent lots in use. Participant 18 only submitted data for Optitrol ToRCH M DM20144.

Figures 5 and 6 show data from Participants 1304 and 1072 for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot, showing consistent data entry at IV 3.50, each participant had only one reagent lot in use. Participant 1304 only submitted data for Optitrol ToRCH M DM20144. Figure 7 shows Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by reagent lot, illustrating expected variation of data both within and between the two reagent lots reported. Figure 8 shows Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 and DM20144 by reagent lot, highlighting the unexpected consistency and lack of spread or variation of data reported for Optitrol ToRCH M DM20014.

Participant 1326 was identified as part of the peer group for the DiaSorin LIAISON HSV-1/2 IgM assay, however as observed in Figure 9, has only been reporting data for Optitrol ToRCH M DM19030 with expected data variation across the two reagent lots in use. A previous investigation into data reported at IV 3.50 for Optitrol ToRCH M DM19030 concluded that the QC had not been used according to the IFU and these data were made invalid. Participant 1326 has not reported any data for Optitrol ToRCH M DM20144.

Figures 10 through 27 show data for all other assays testing with Optitrol ToRCH M DM20144 across the following platforms, DiaSorin LIAISON, Abbott Alinity i, Abbott ARCHITECT, Ortho VITROS, Roche Elecsys, Siemens ATELLICA and Novagност. All data reported show the expected spread and variation across all reagent lots in use. The issue identified on the

DiaSorin LIAISON HSV-1/2 IgM assay was not observed on any other assay recorded in EDCNet.

NRL contacted DaiMex to investigate the issue and was notified that, Optitrol ToRCH M DM20144 cannot be used as a control nor as a patient sample on the DiaSorin LIAISON HSV-1/2 IgM assay, as it was found to have some interferences and was potentially not suitable for this assay.

RECOMMENDATIONS

NRL to make all data reported for Optitrol ToRCH M DM20144 with the DiaSorin LIAISON HSV-1/2 IgM assay in EDCNet invalid.

NRL to contact Australian Participants testing Optitrol ToRCH M DM20144 with the DiaSorin LIAISON HSV-1/2 IgM assay informing them of the unsuitability of this QC lot with this assay.

NRL will replace provided kits of Optitrol ToRCH M DM20144 for Australian participants. Providing them with replacement stock of Optitrol ToRCH M DM21174, informing participants that from this QC lot (DM21174) onwards this QC is to be run as a control and to refer to the IFU for details.

NRL to contact the appropriate DaiMex distributors relaying the findings of this report and recommending then to contact the relevant participants and provide replacement stock and information.

NRL to continue to monitor the DiaSorin LIAISON HSV-1/2 IgM assay to ensure Optitrol ToRCH M DM21174 is running as expected and participants are testing as per IFU.

NRL to requests that for any future QC that may be deemed unsuitable for one or more of the assays it is recommended for be communicated to NRL prior to release.

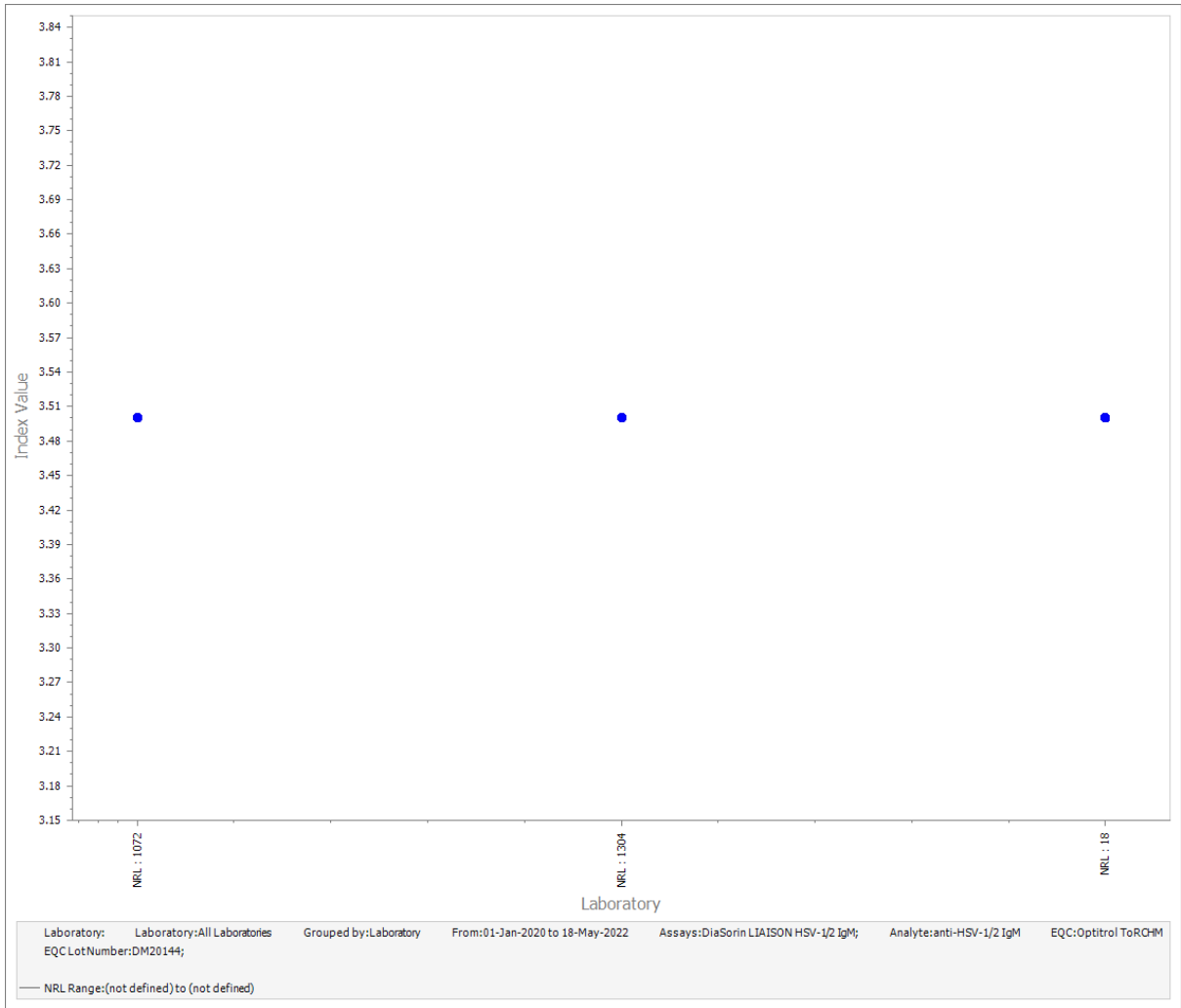


Figure 1 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by participant.

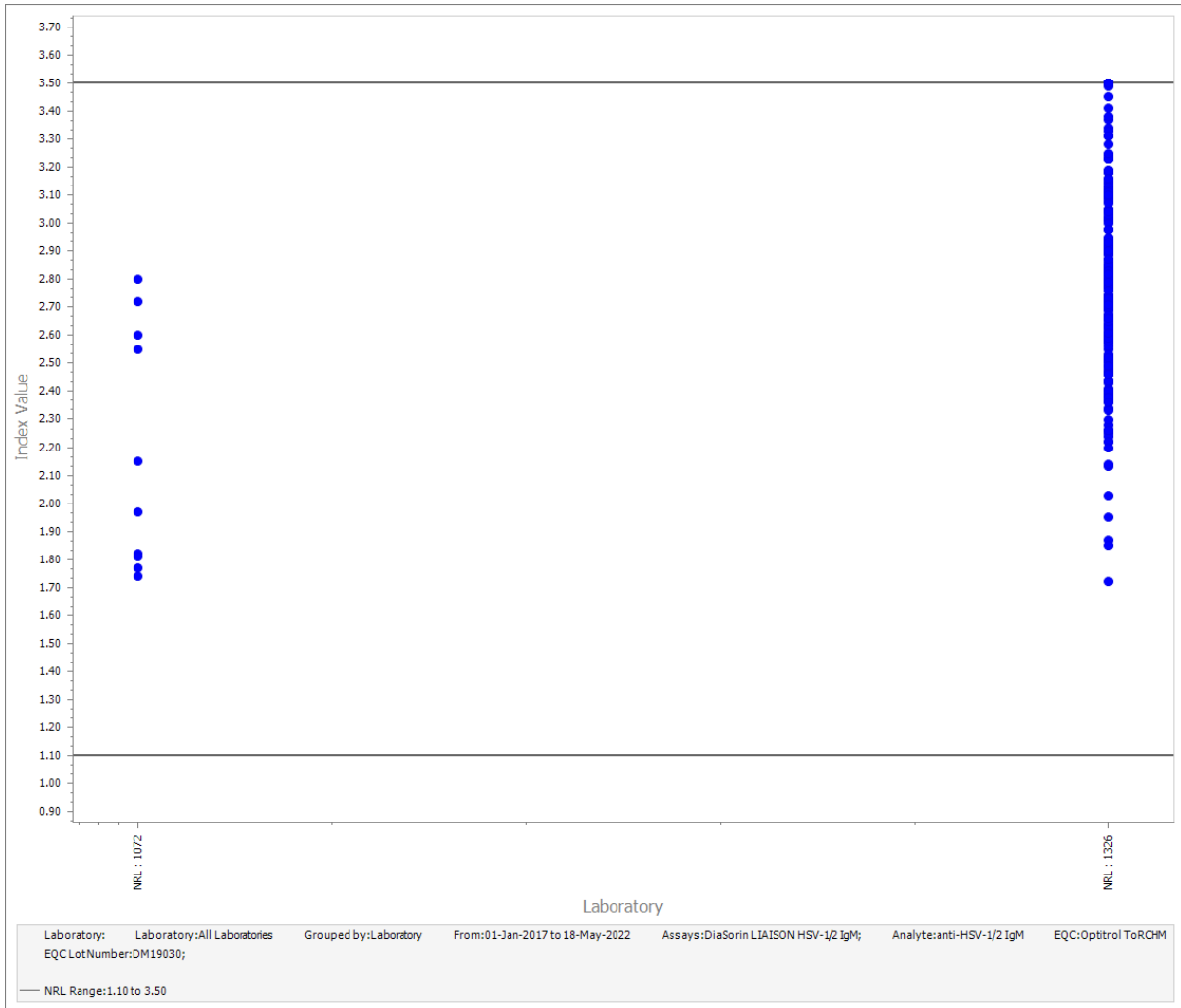


Figure 2 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by participant.

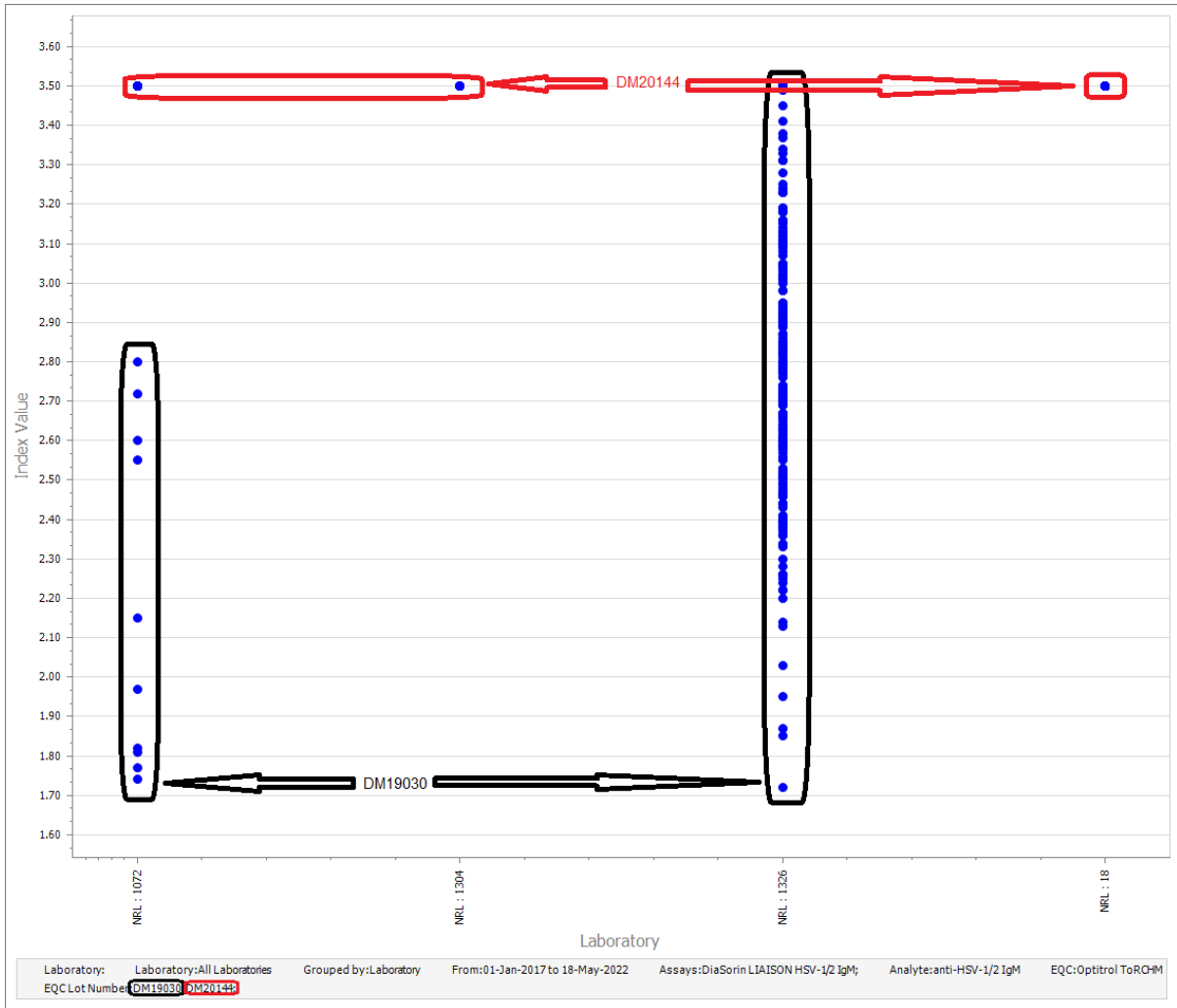


Figure 3 – Peer group data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 and DM20144 by participant.

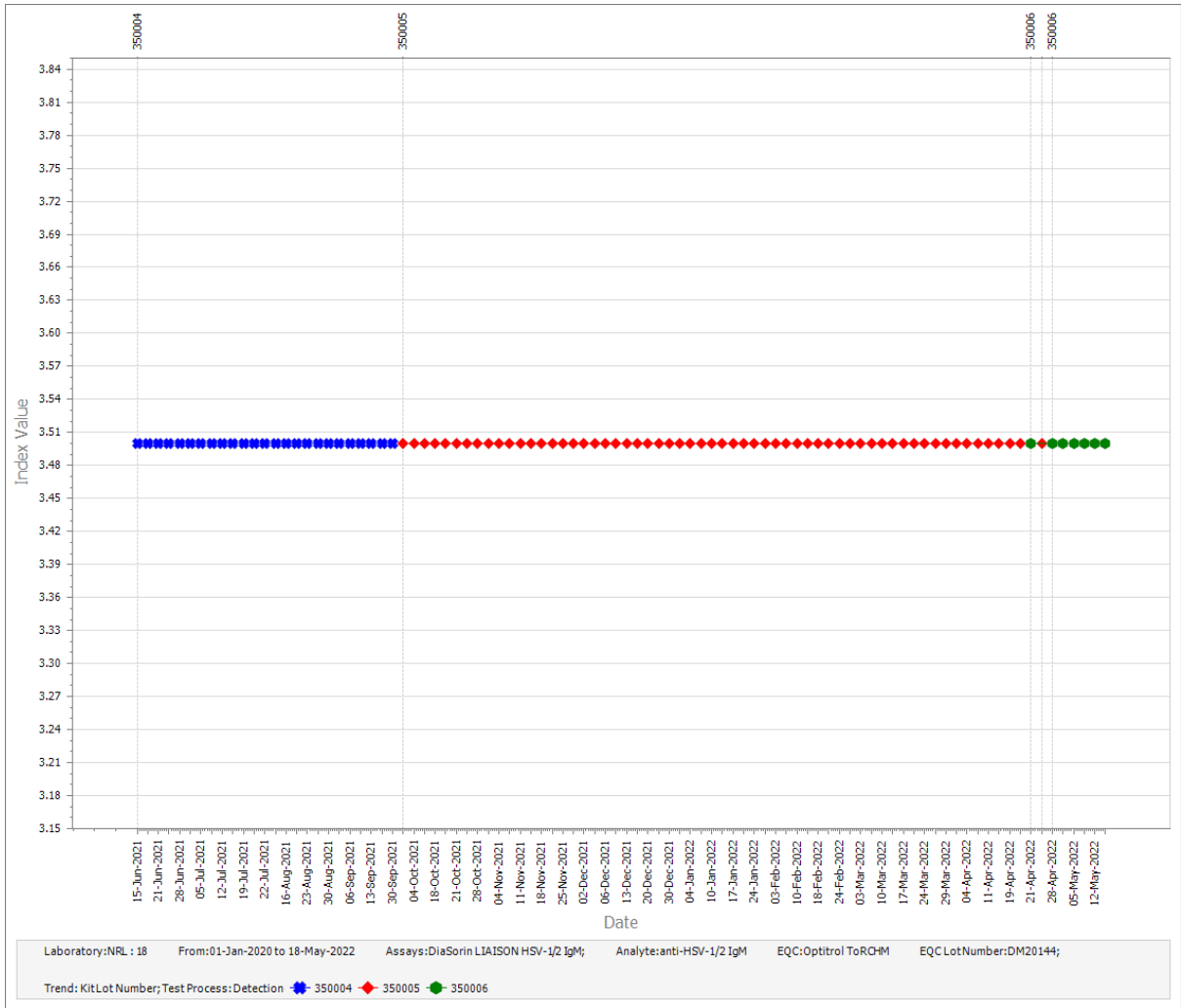


Figure 4 – Participant 18 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.

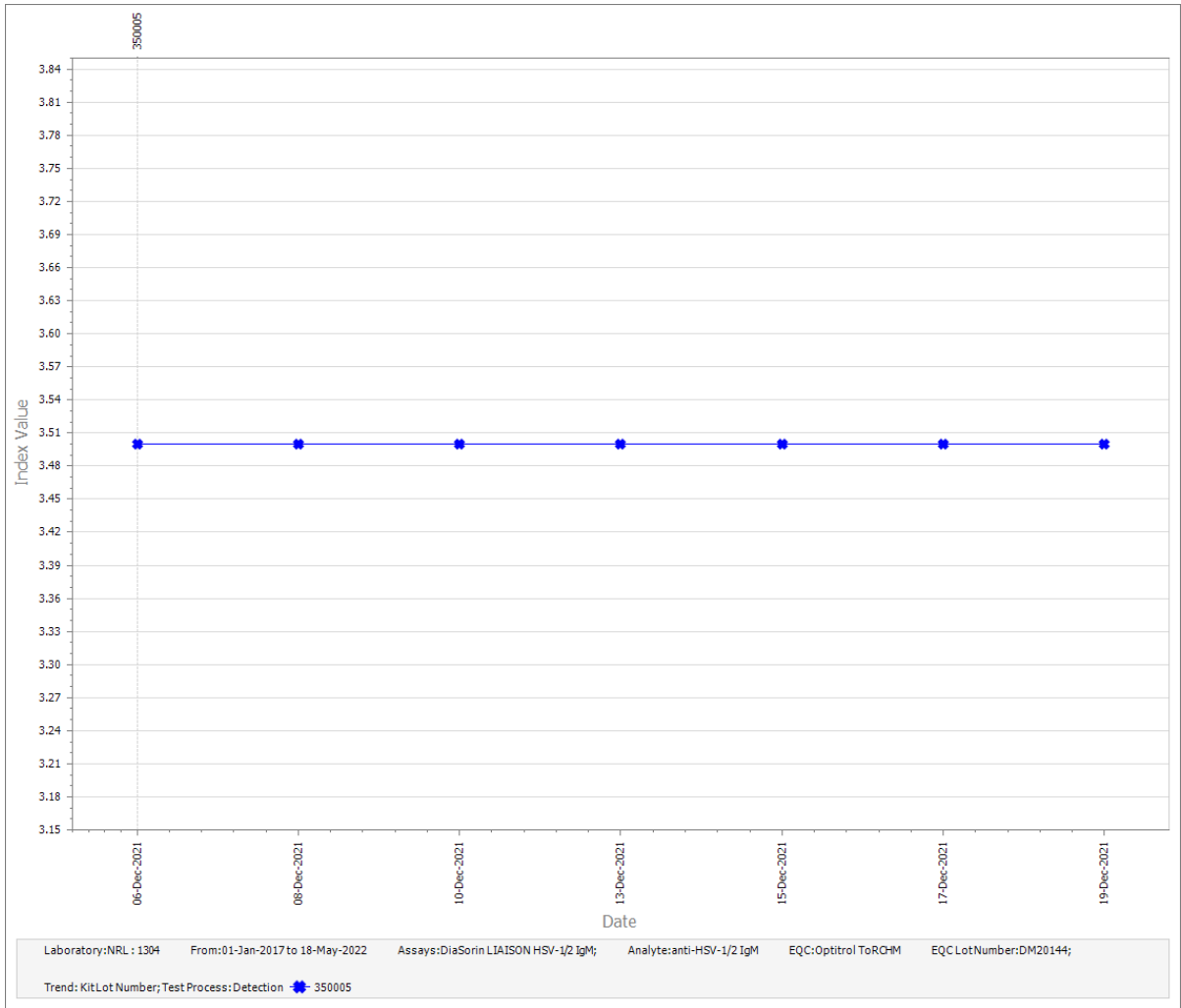


Figure 5 – Participant 1304 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.

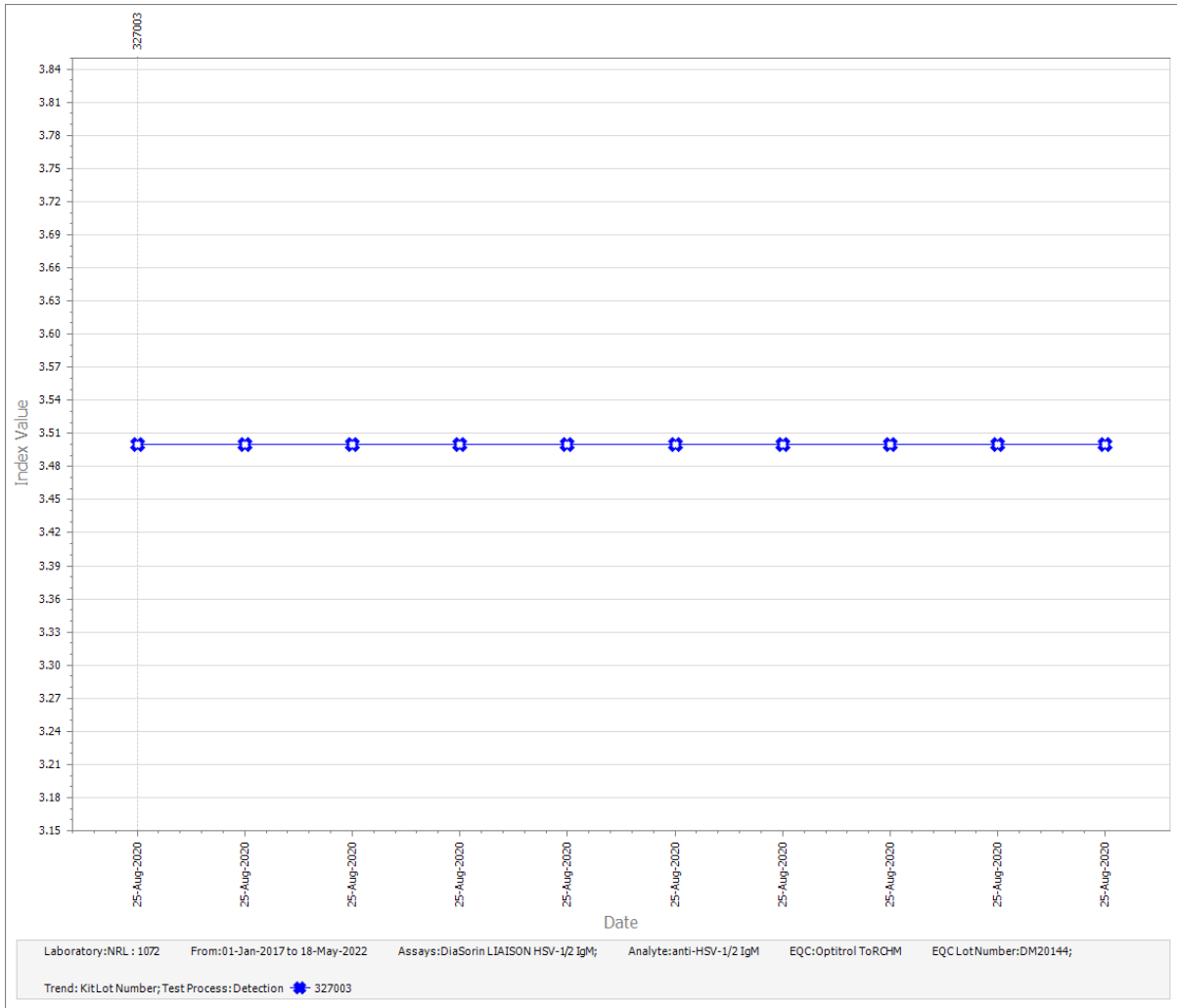


Figure 6 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM20144 by reagent lot.

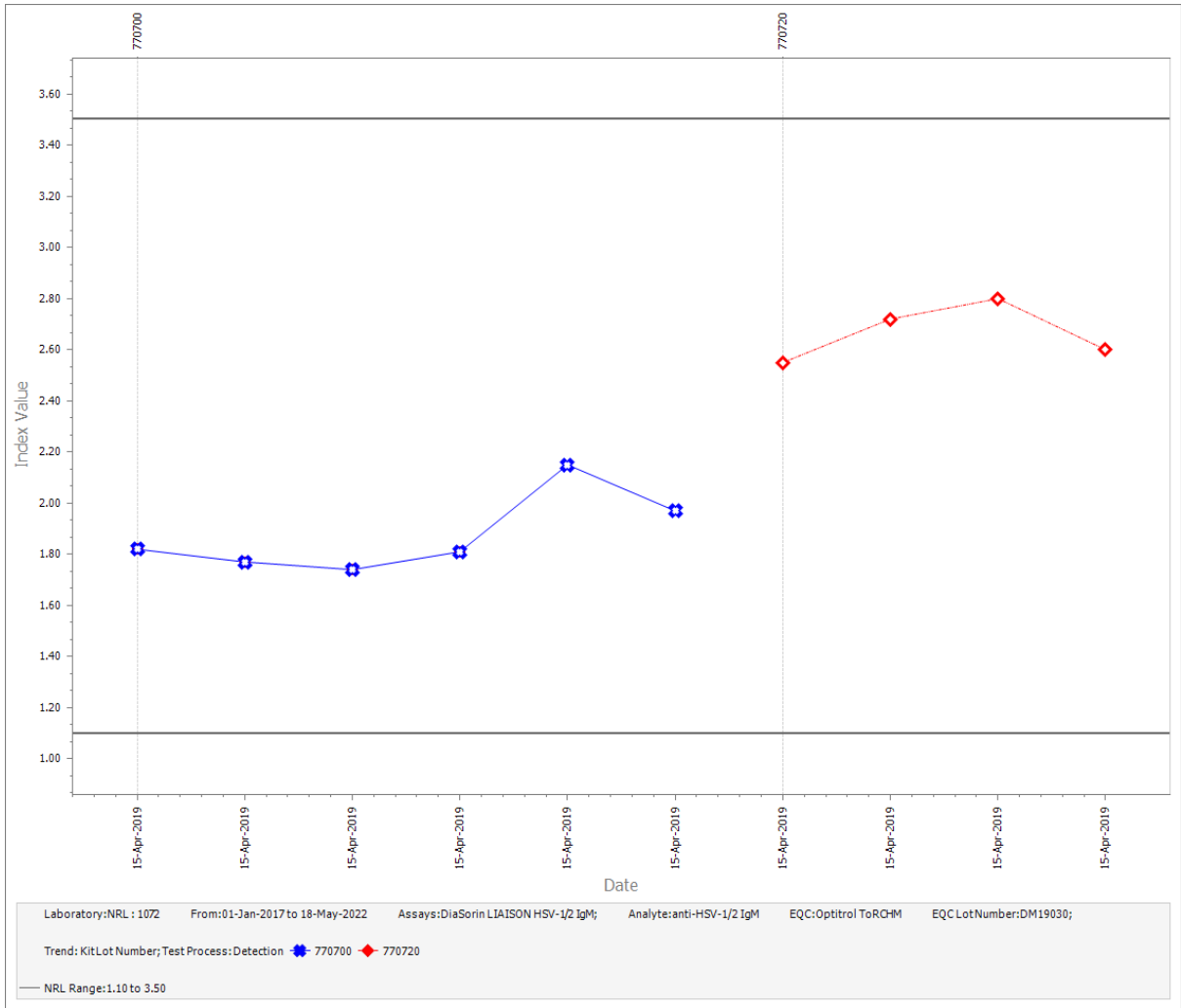


Figure 7 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by reagent lot.

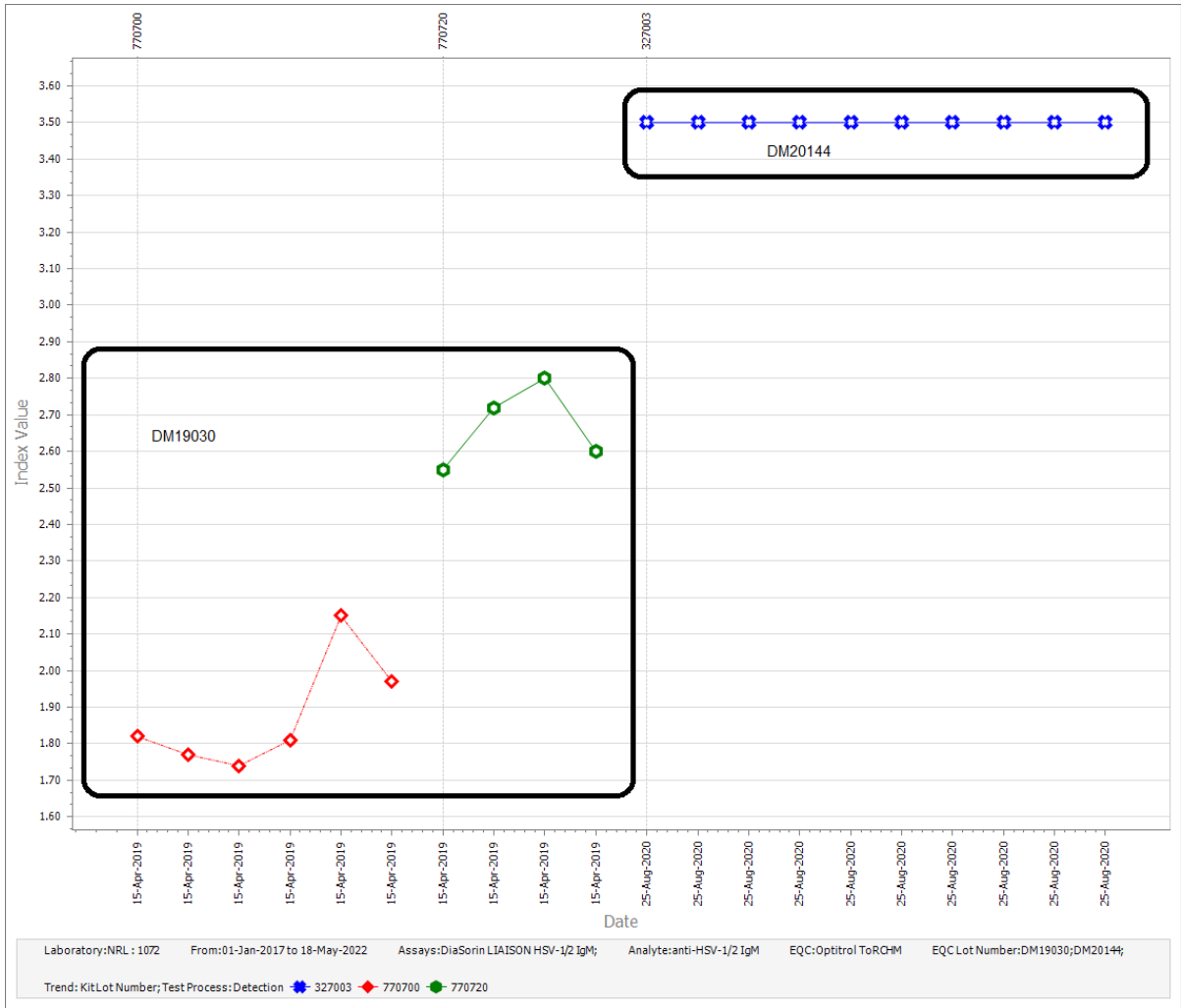


Figure 8 – Participant 1072 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 and DM20144 by reagent lot.

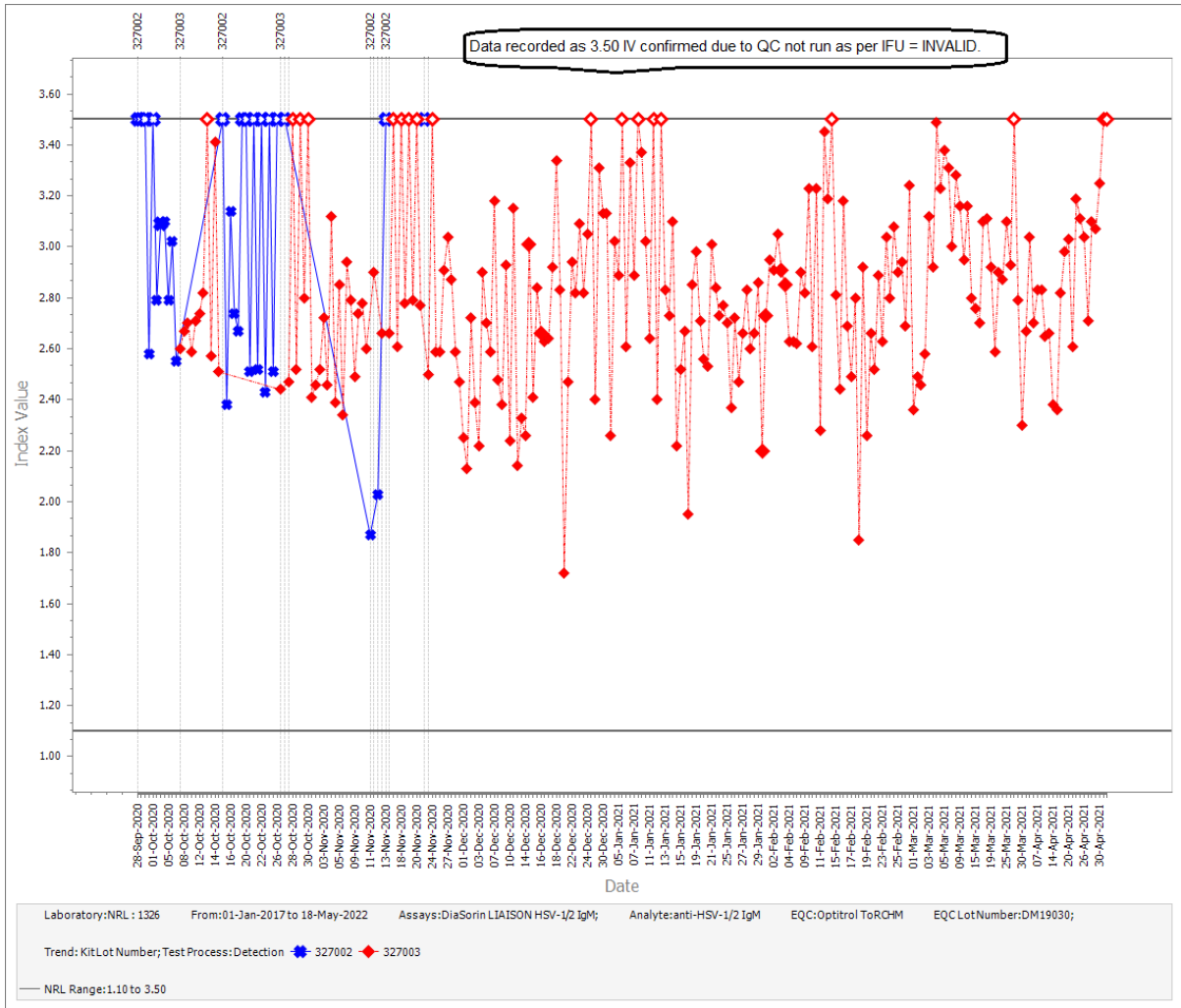


Figure 9 – Participant 1026 data for DiaSorin LIAISON HSV-1/2 IgM, Optitrol ToRCH M DM19030 by reagent lot.

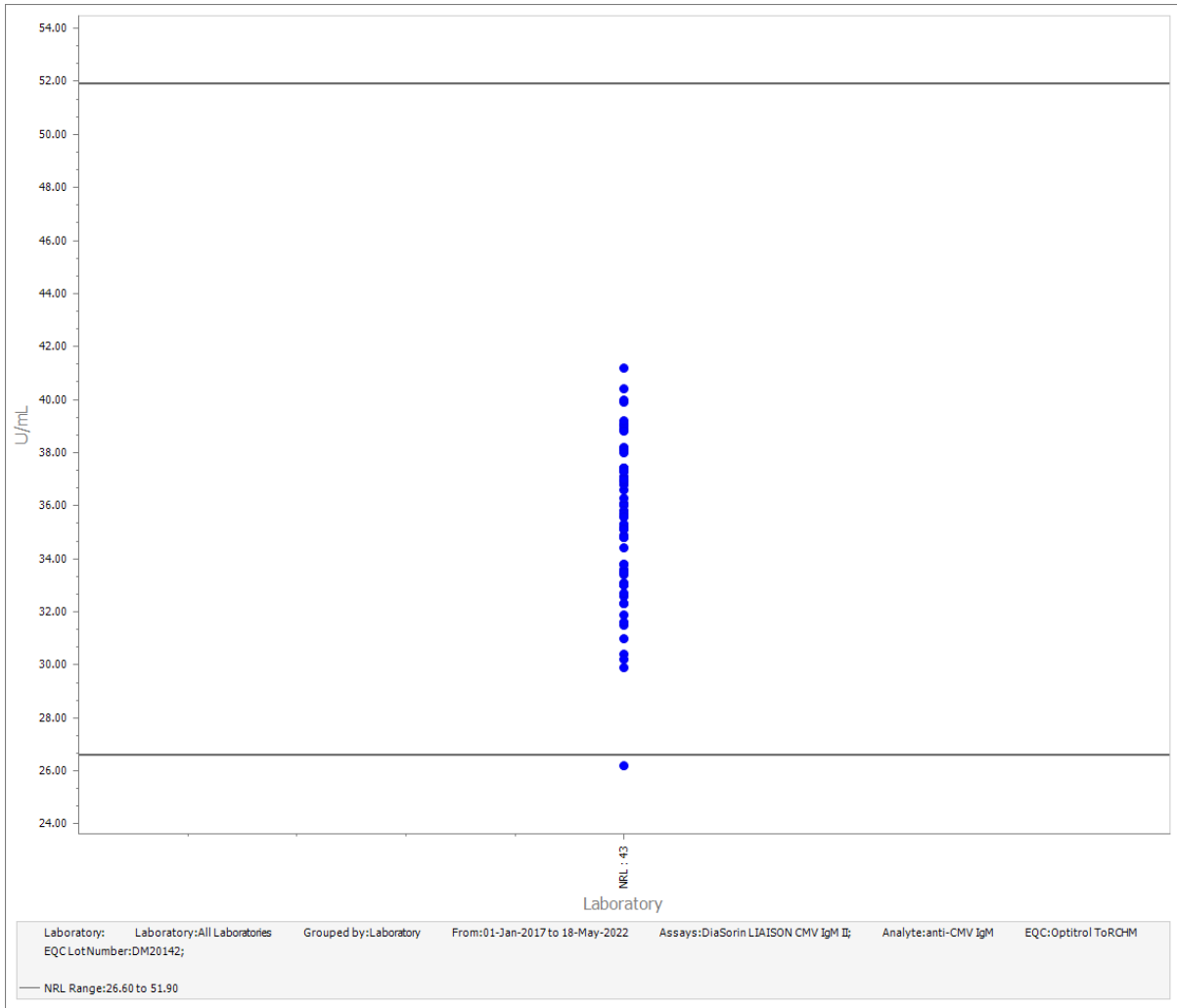


Figure 10 – Peer group data for DiaSorin LIAISON CMV IgM II, Optitrol ToRCH M DM20144 by participant.

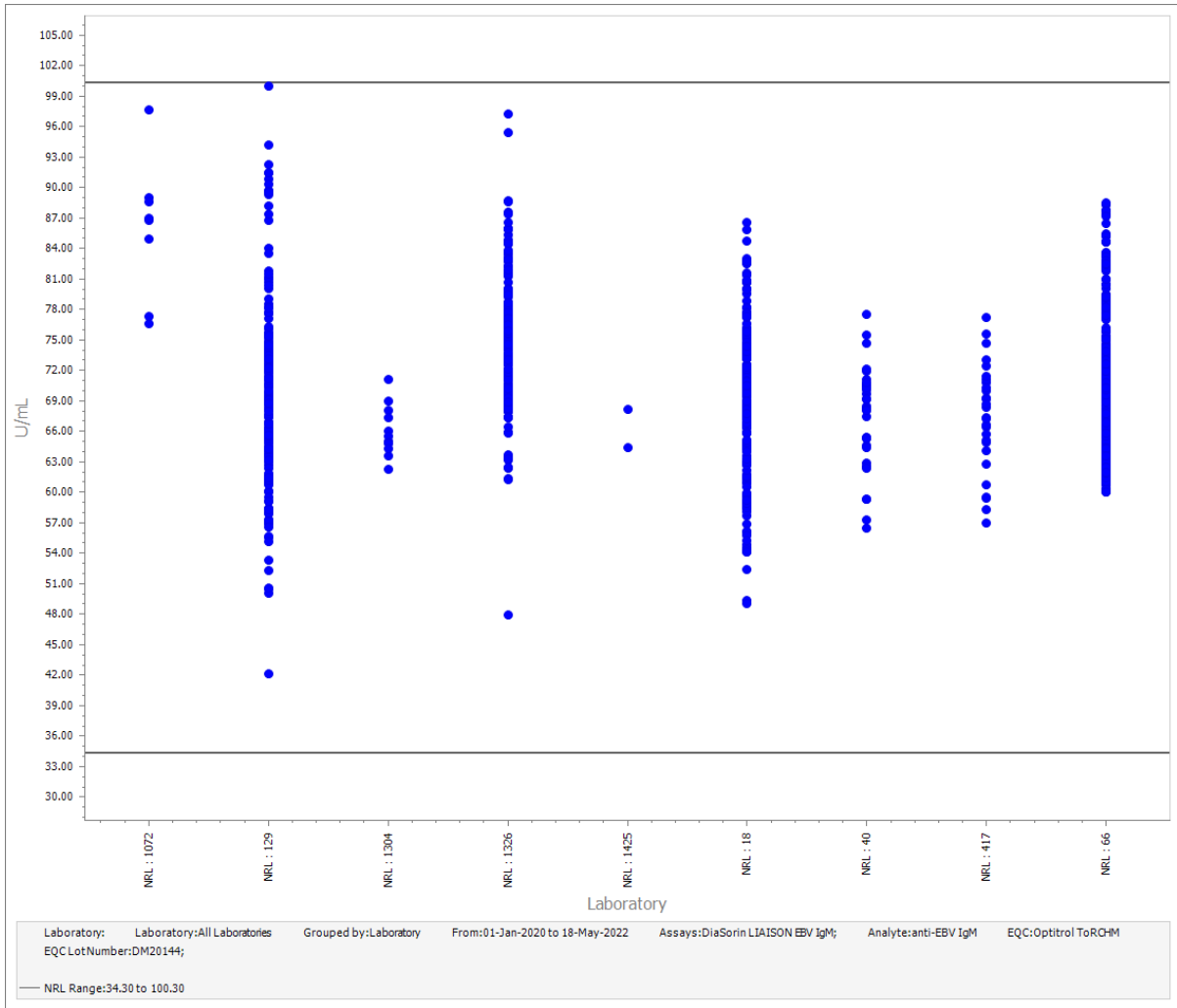


Figure 11 – Peer group data for DiaSorin LIAISON EBV IgM, Optitrol ToRCH M DM20144 by participant.

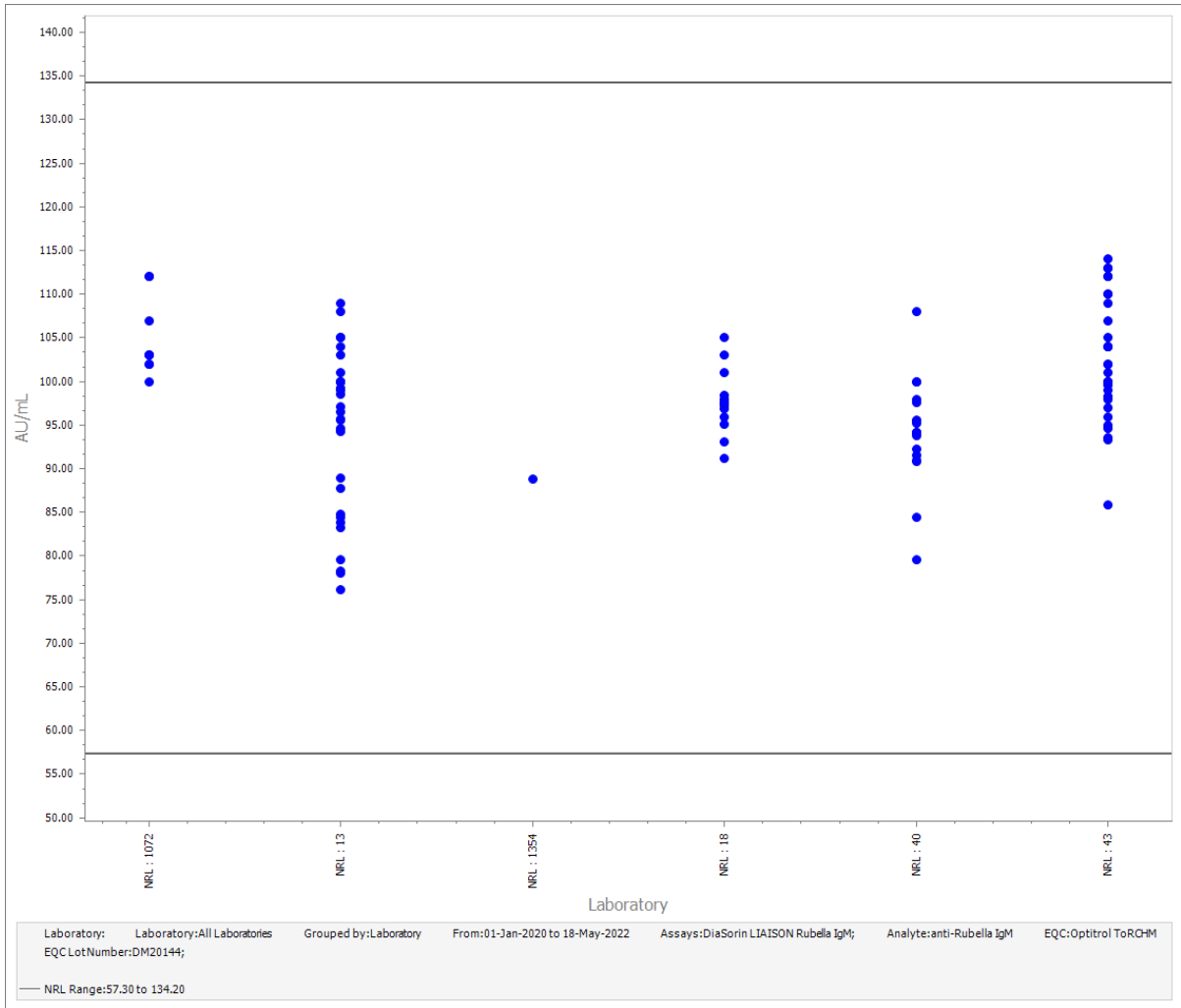


Figure 12 – Peer group data for DiaSorin LIAISON Rubella IgM, Optitrol ToRCH M DM20144 by participant.

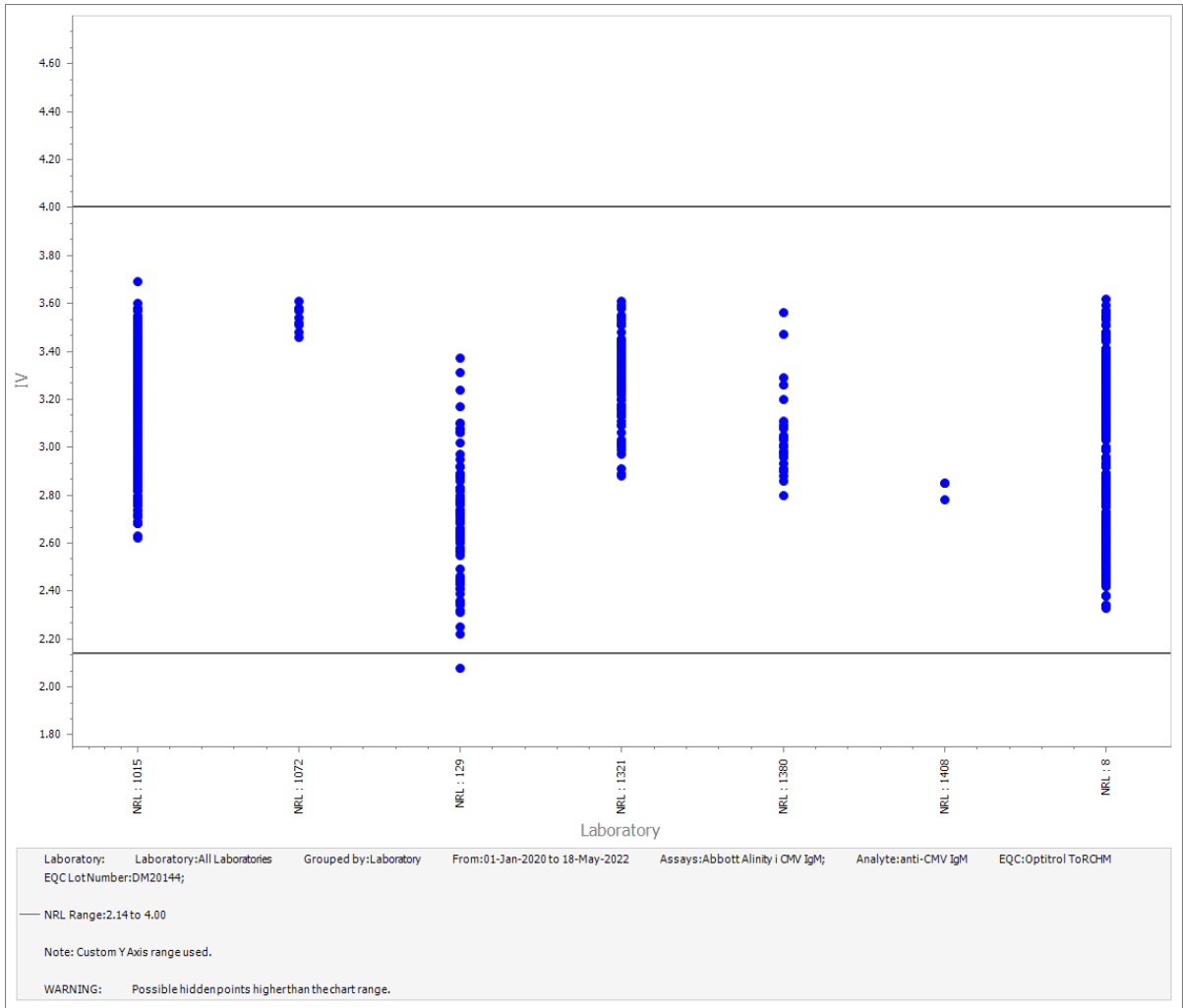


Figure 13 – Peer group data for Abbott Alinity i CMV IgM, Optitrol ToRCH M DM20144 by participant.

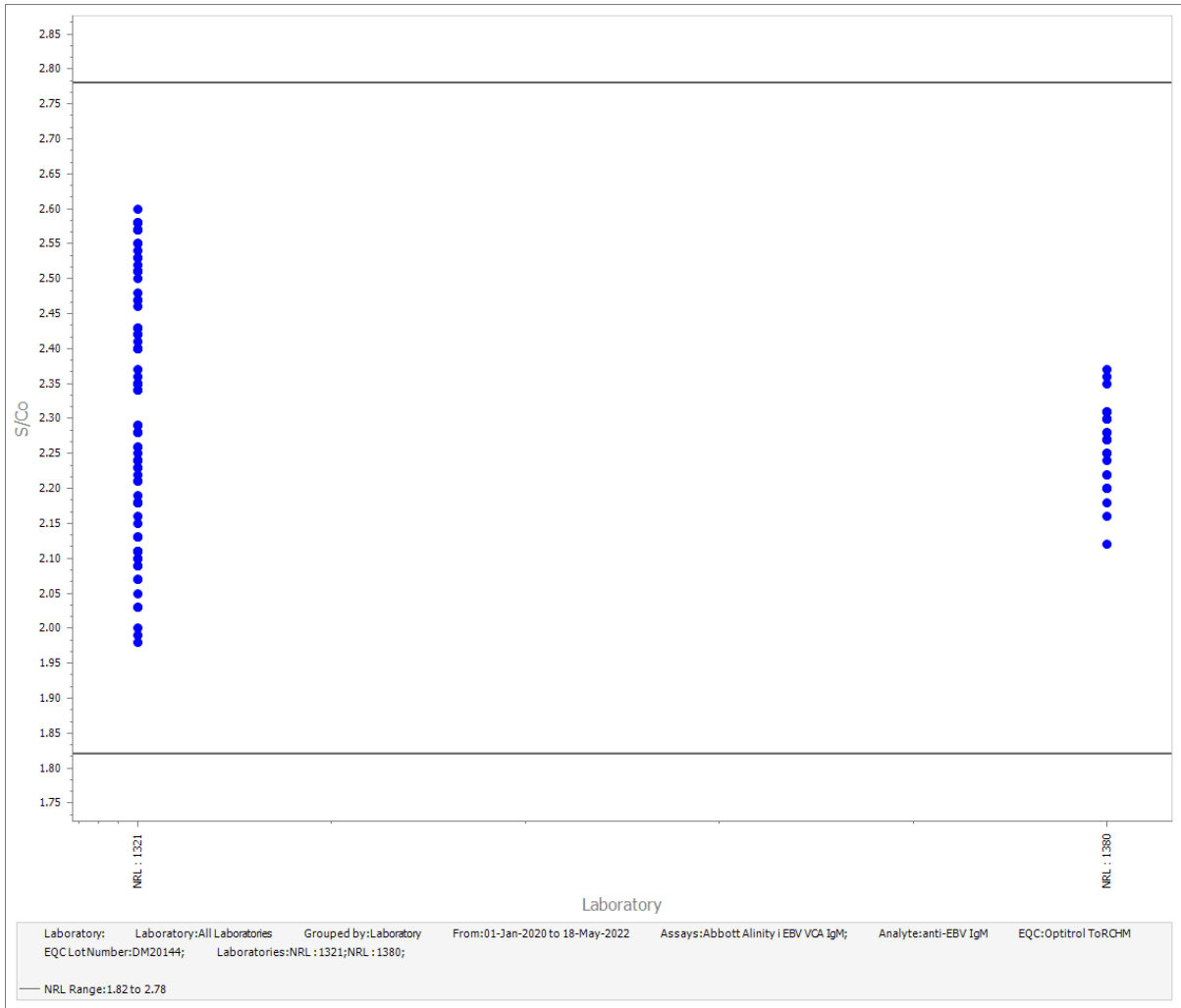


Figure 14 – Peer group data for Abbott Alinity i EBV VCA IgM, Optitrol ToRCH M DM20144 by participant.

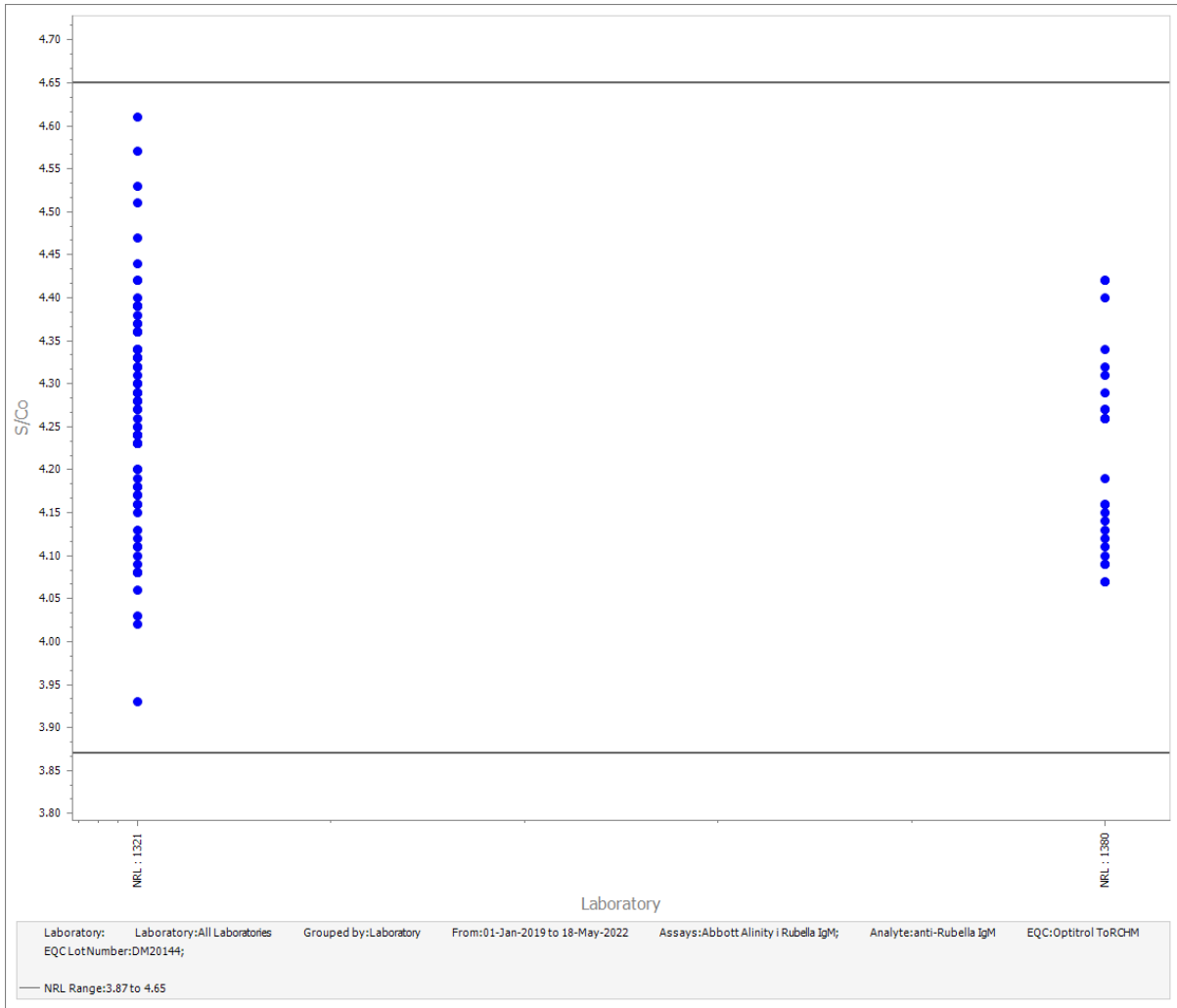


Figure 15 – Peer group data for Abbott Alinity i Rubella IgM, Optitrol ToRCH M DM20144 by participant.

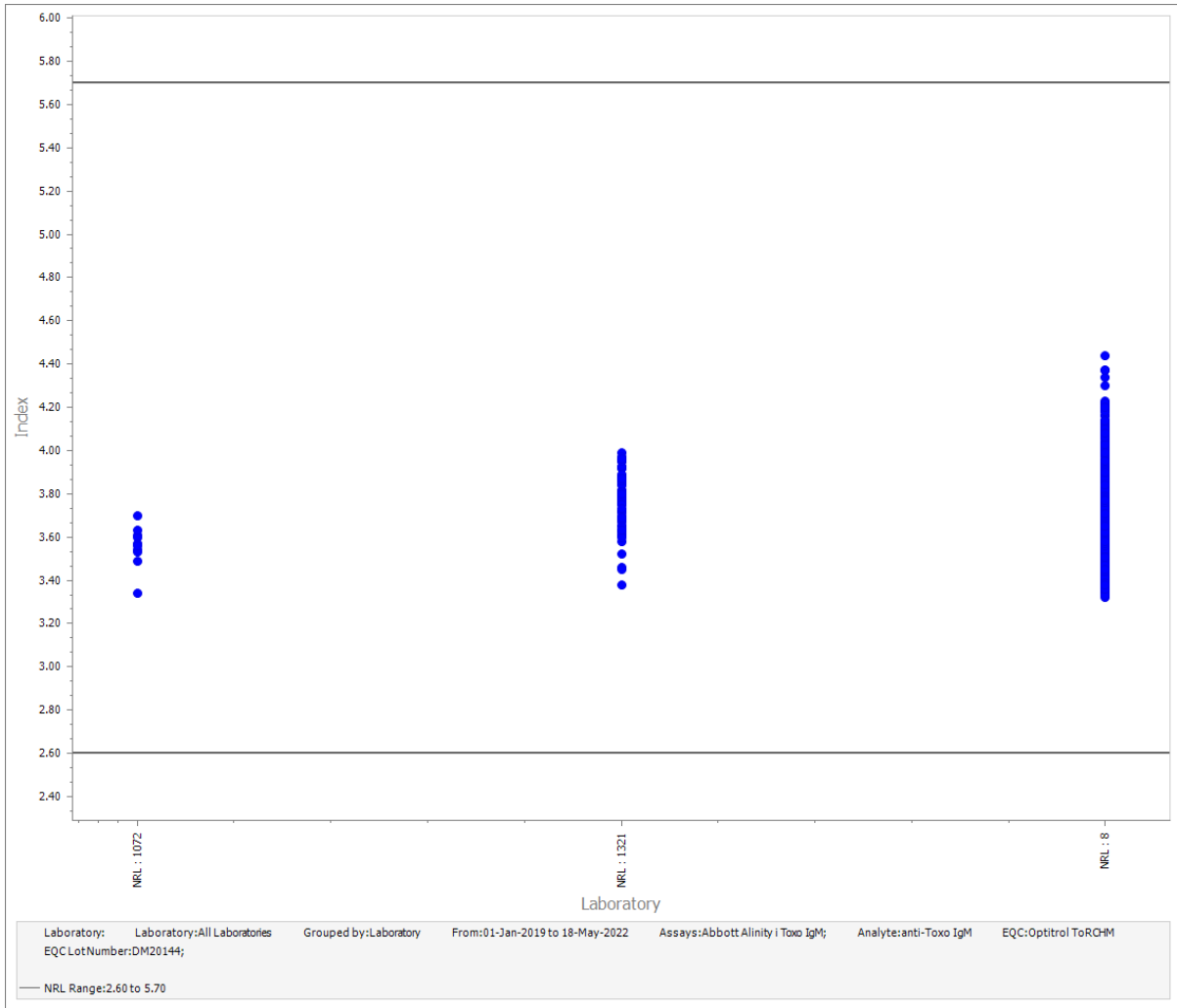


Figure 16 – Peer group data for Abbott Alinity i Toxo IgM, Optitrol ToRCH M DM20144 by participant.

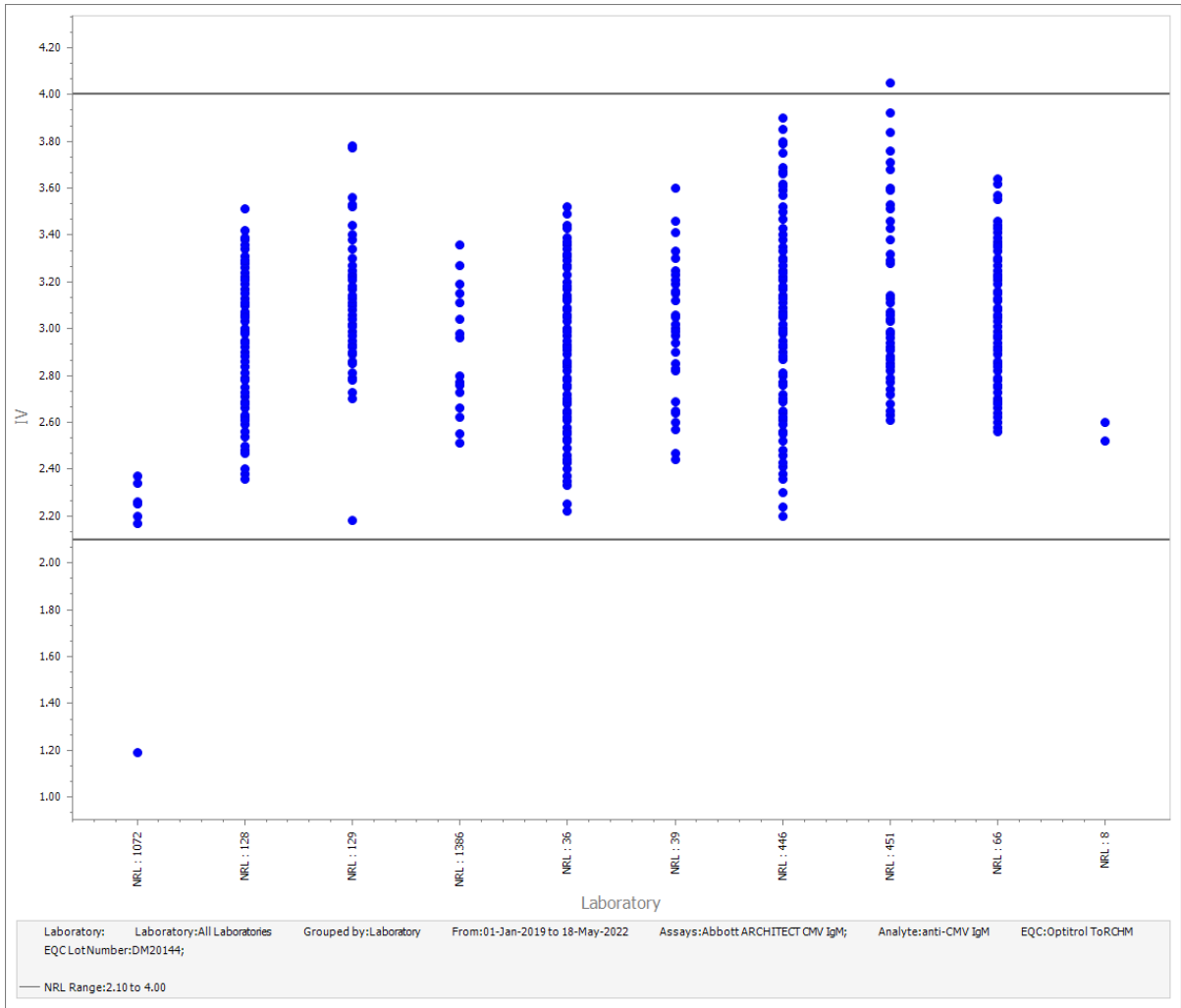


Figure 17 – Peer group data for Abbott ARCHITECT CMV IgM, Optitrol ToRCH M DM20144 by participant.

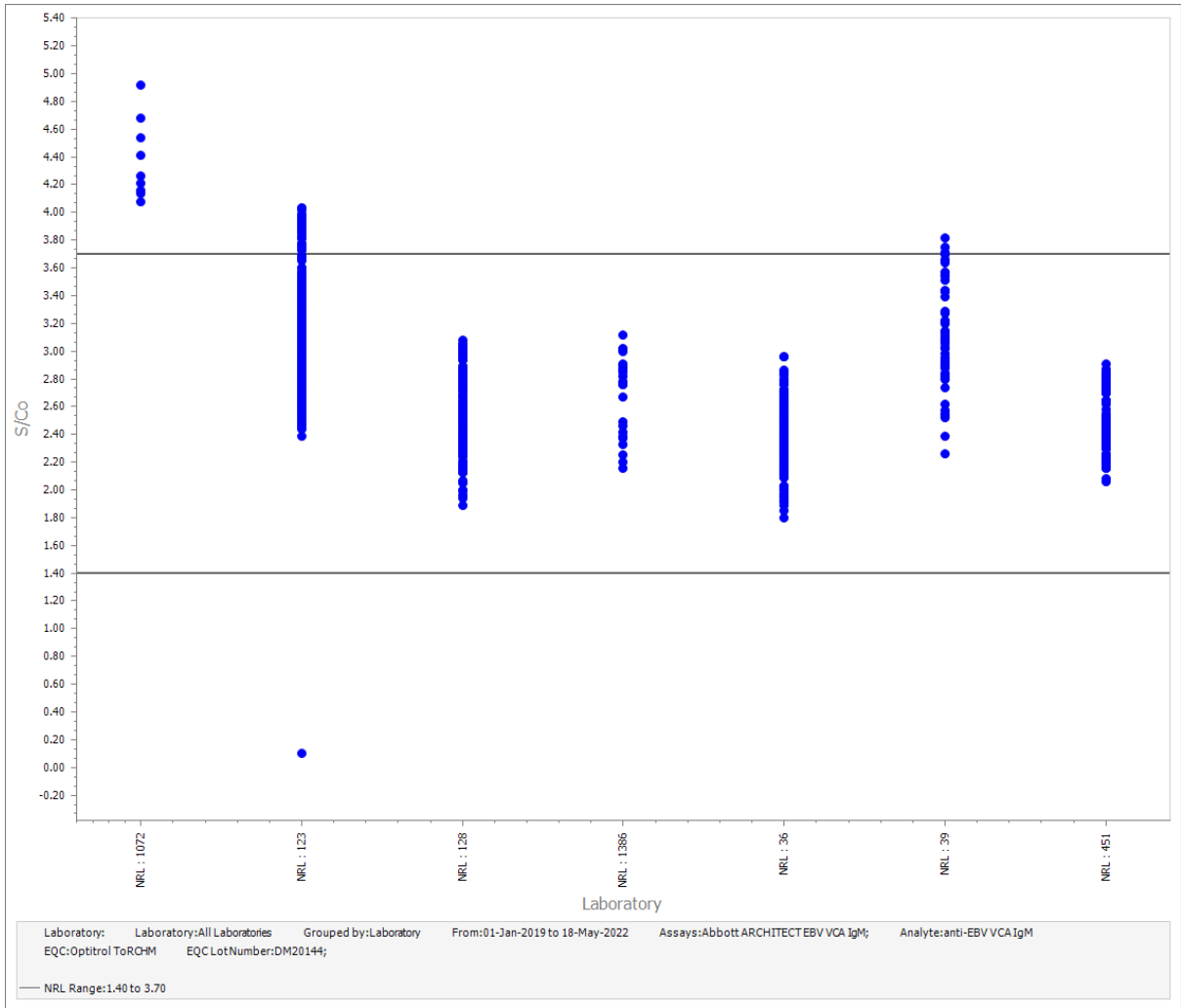


Figure 18 – Peer group data for Abbott ARCHITECT EBV VCA IgM, Optitrol ToRCH M DM20144 by participant.

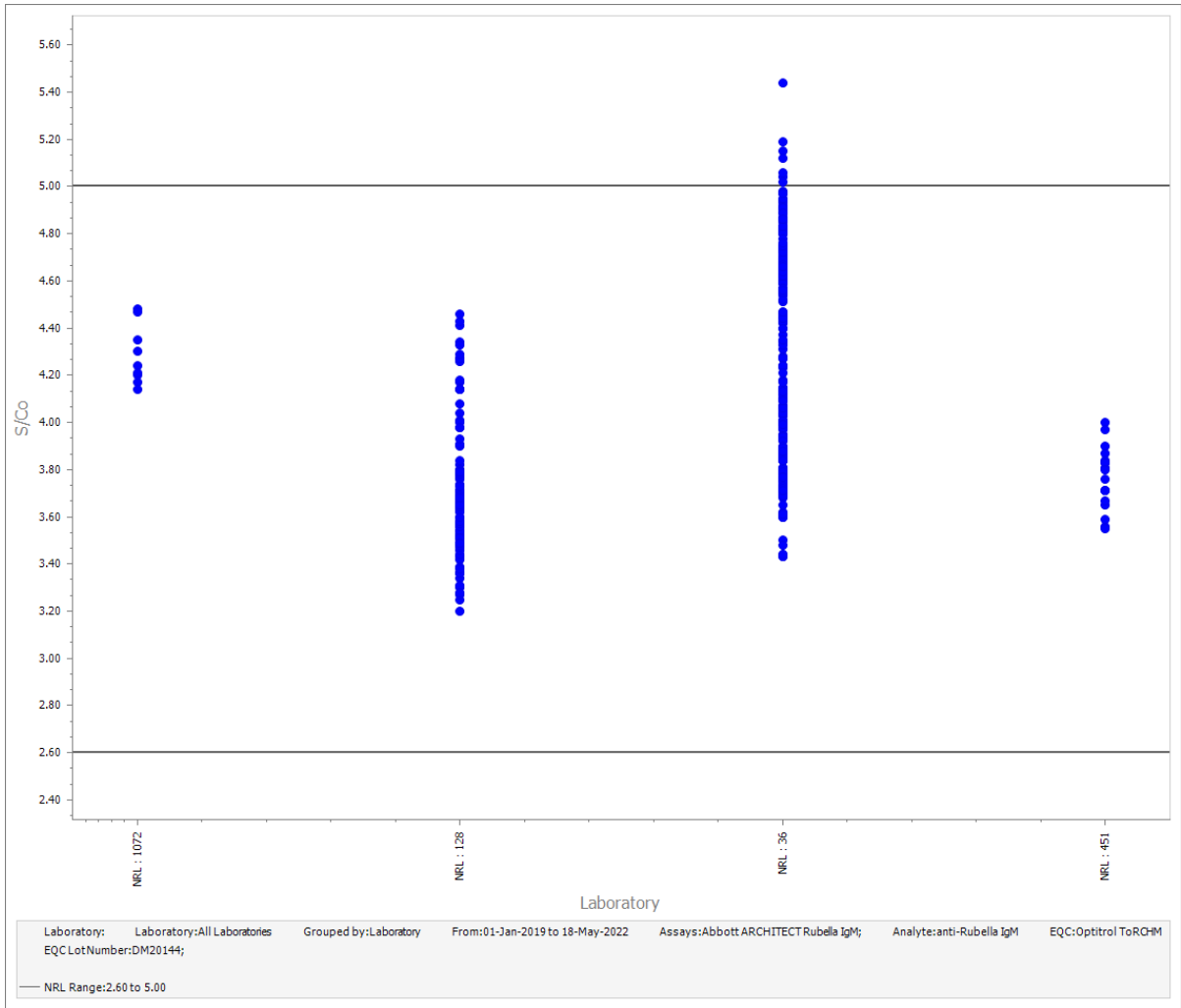


Figure 19 – Peer group data Abbott ARCHITECT Rubella IgM, Optitrol ToRCH M DM20144 by participant.

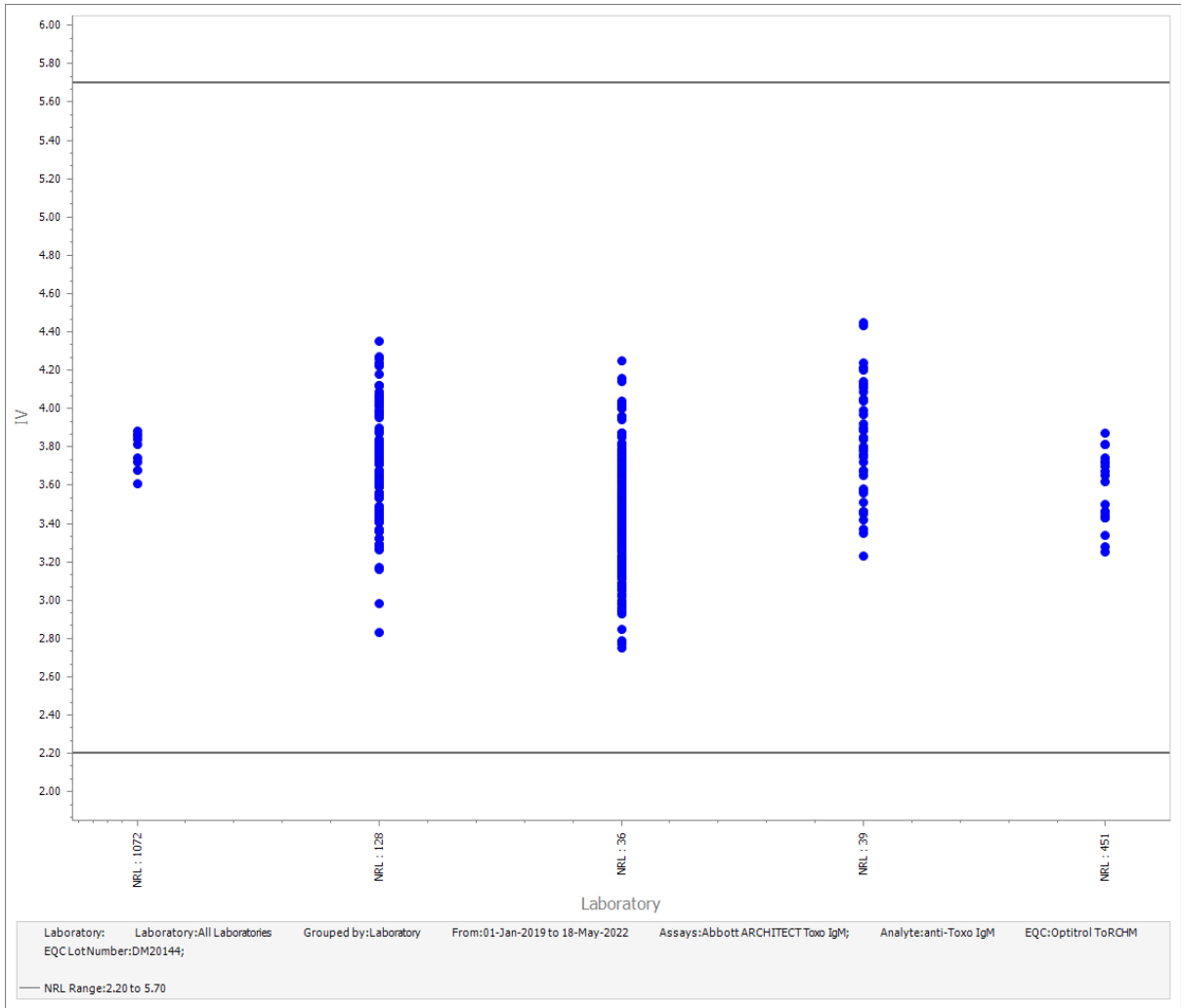


Figure 20 – Peer group data Abbott ARCHITECT Toxo IgM, Optitrol ToRCH M DM20144 by participant.

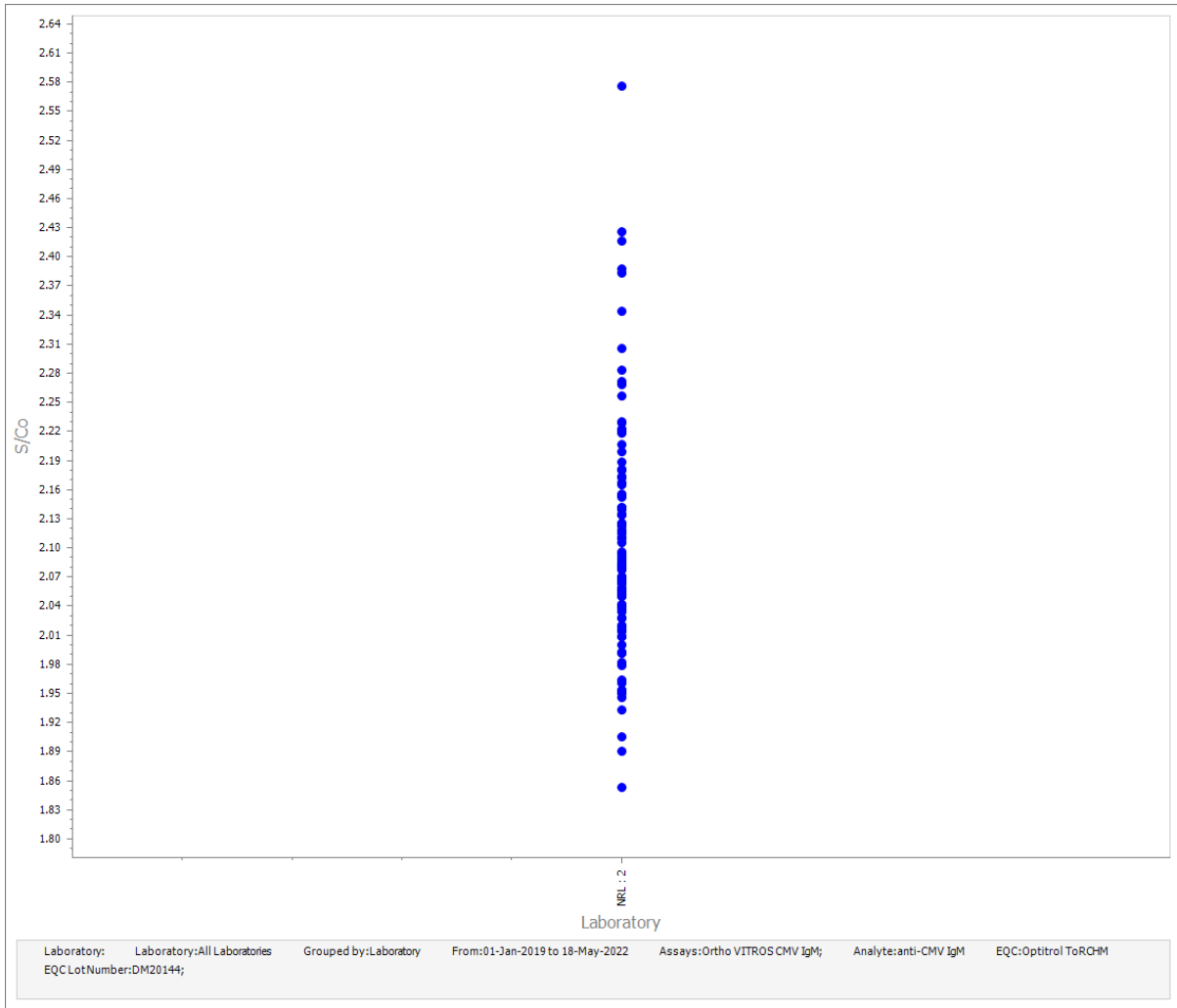


Figure 21 – Peer group data for Ortho VITROS CMV IgM, Optitrol ToRCH M DM20144 by participant.

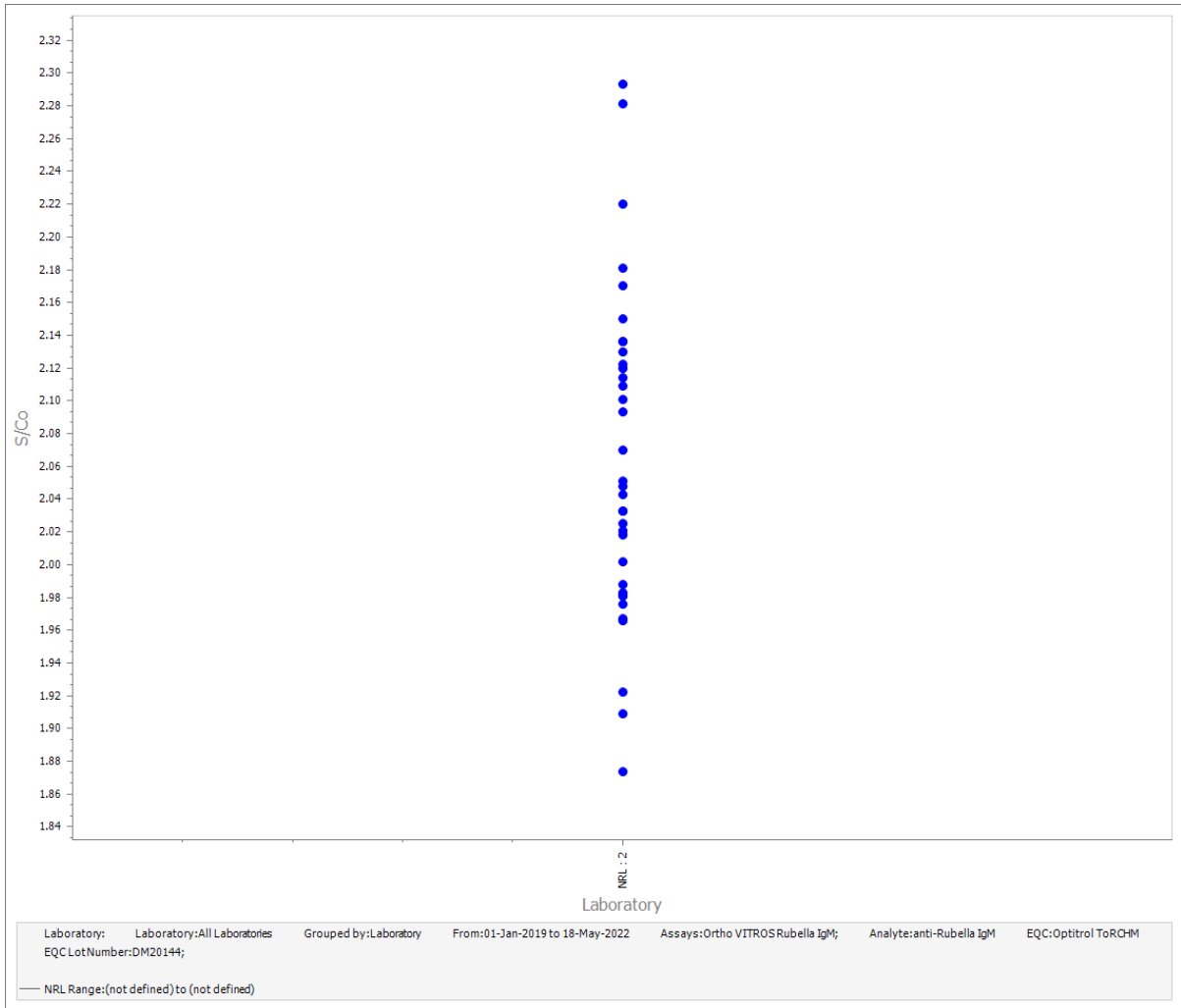


Figure 22 – Peer group data for Ortho VITROS Rubella IgM, Optitrol ToRCH M DM20144 by participant.

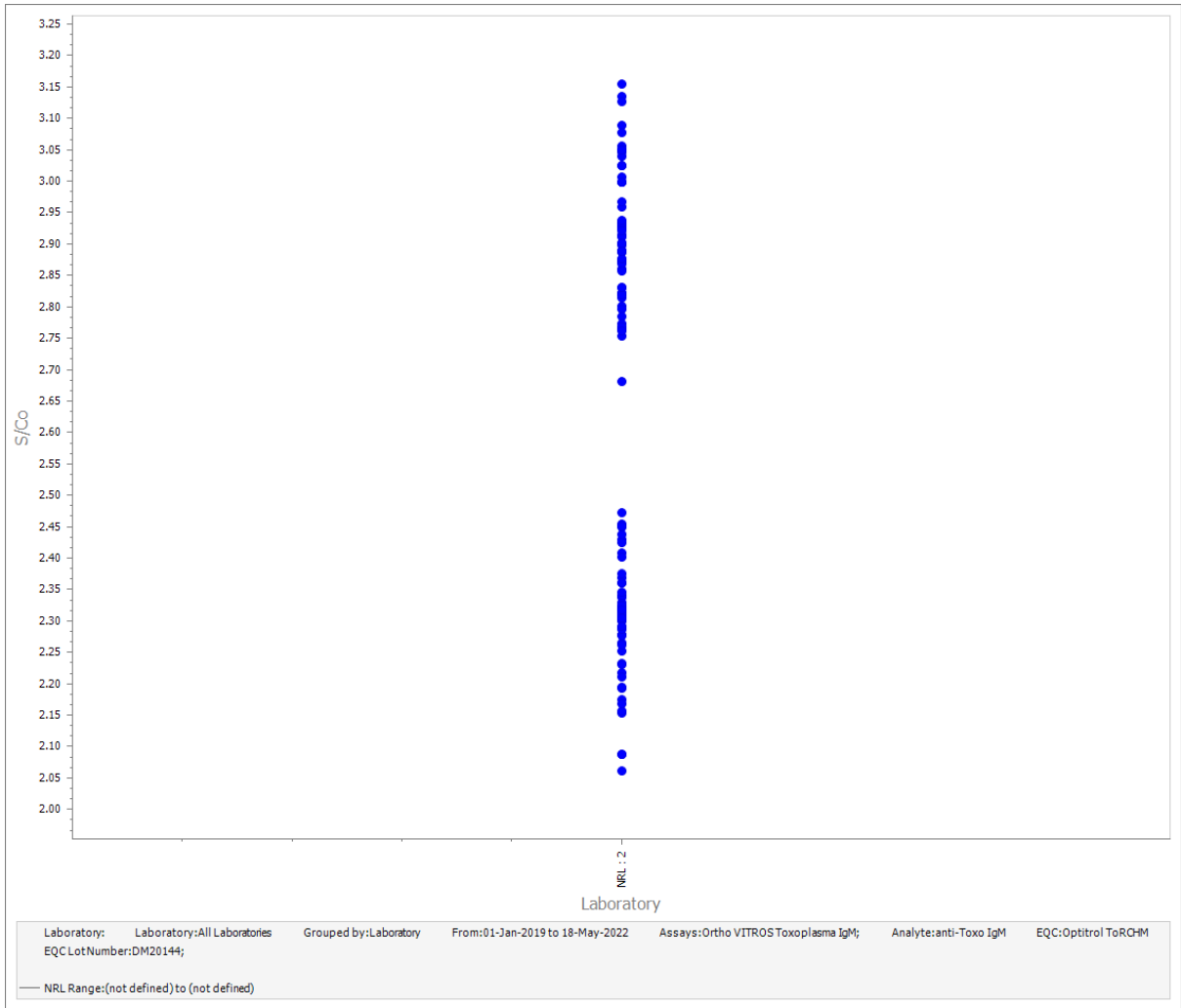


Figure 23 – Peer group data for Ortho VITROS Toxoplasma IgM, Optitrol ToRCH M DM20144 by participant.

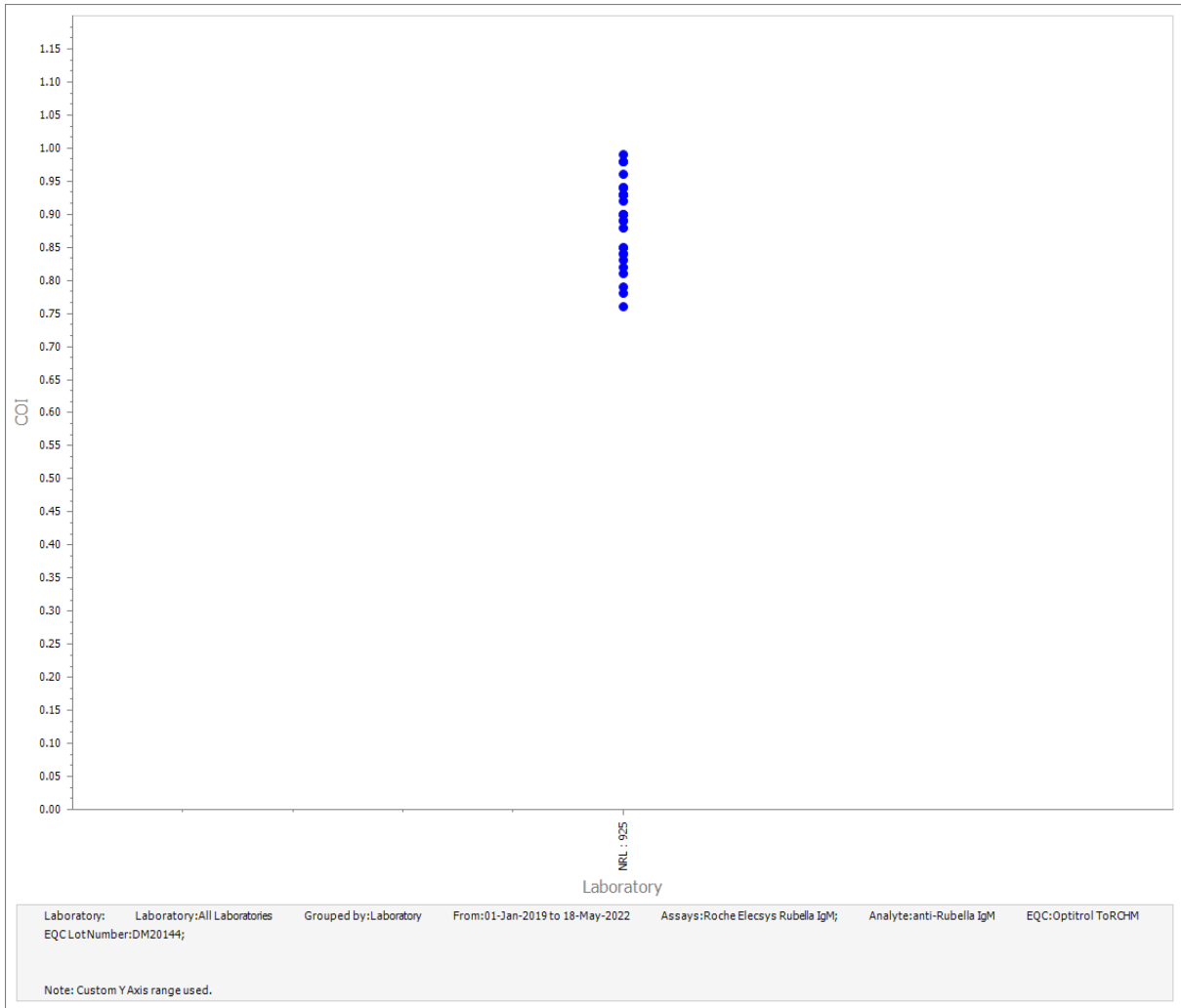


Figure 24 – Peer group data for Roche Elecsys Rubella IgM, Optitrol ToRCH M DM20144 by participant.

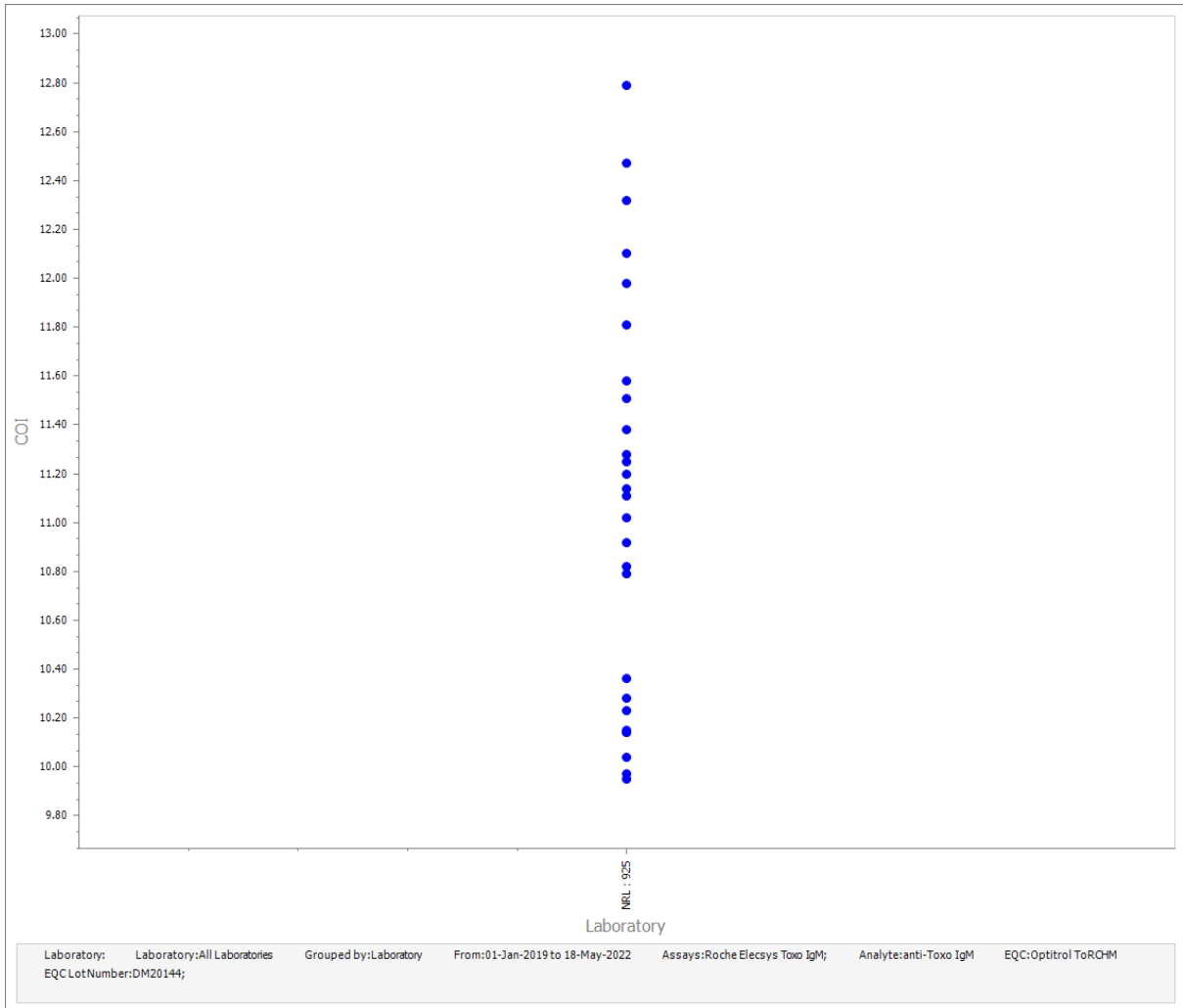


Figure 25 – Peer group data for Roche Elecsys Toxo IgM, Optitrol ToRCH M DM20144 by participant.

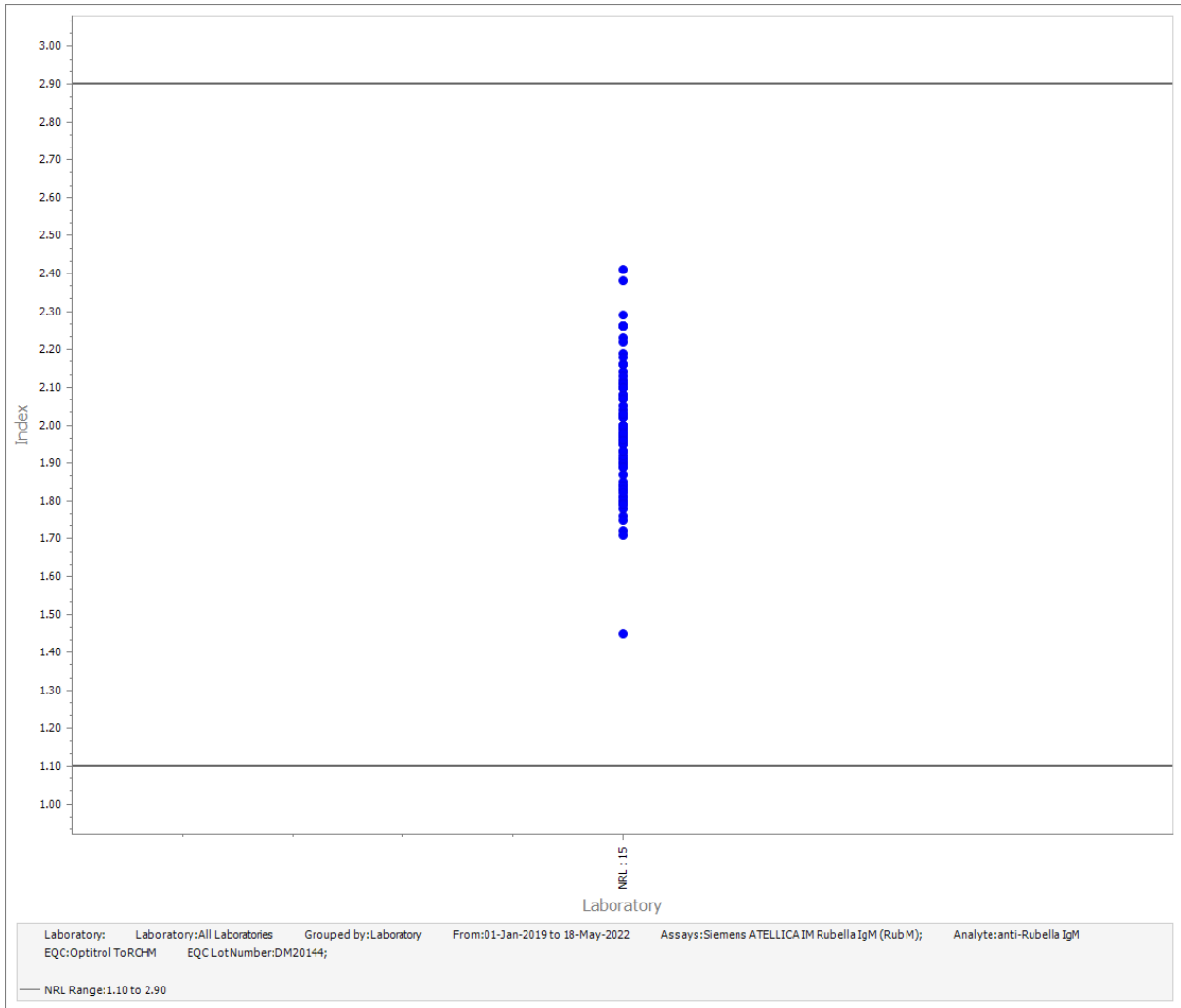


Figure 26 – Peer group data for Siemens ATELLICA IM Rubella IgM (Rub M), Optitrol ToRCH M DM20144 by participant.

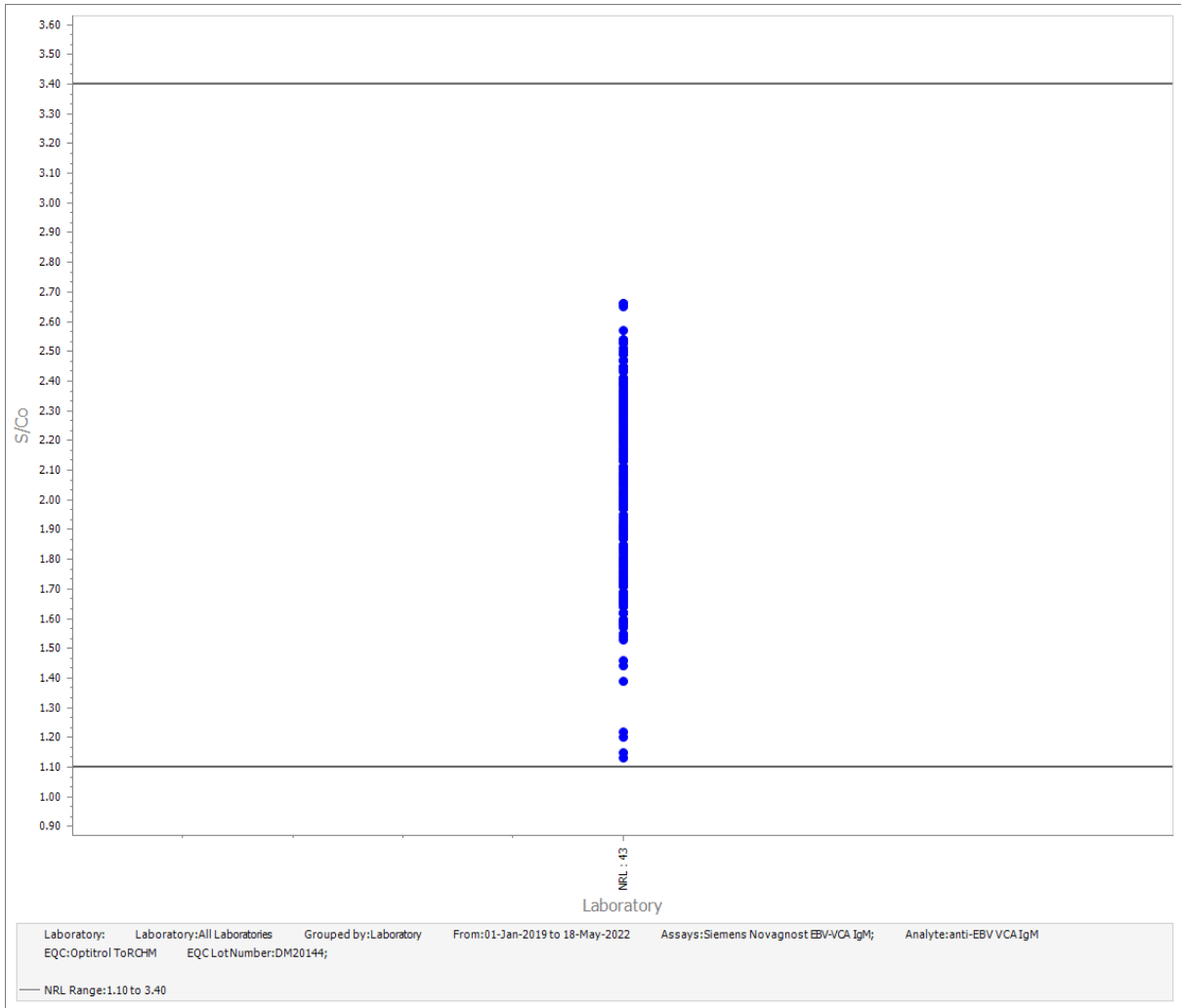


Figure 27 – Peer group data for Siemens Novagnost EBV-VCA IgM, Optitrol ToRCH M DM20144 by participant.