

QC Services Investigation: PMM-QC-1583

CONTENTS

INTRODUCTION.....	3
FINDINGS	3-4
DISCUSSION.....	4-5
RECOMMENDATIONS.....	5

Report prepared by: Kylie Davies

Authorised By: Joe Vincini

and distributed in the week beginning 30/OCT/2023

INTRODUCTION

Participant 17 contacted NRL regarding negative S/Co values observed for Optitrol HIVp24 lot DM22200 when testing with the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, on reagent lot 139054. NRL investigated all data reported by the peer group. All Optitrol HIVp24 and reagent lots in use were reviewed, to establish if the negative S/Co values were observed for any other participant, Optitrol HIVp24 or reagent lot.

This report will also review Optitrol HIVp24 DM22200 data reported for the DiaSorin LIAISON XL MUREX HIV Ab/Ag HT, Abbott Alinity s & i HIV Ag/Ab Combo, Abbott ARCHITECT HIV Ag/Ab Combo, bioMerieux VIDAS HIV DUO Ultra, Bio-Rad Access HIV combo V2 & Genscreen HIV-1 Ag EIA (37C/47C), Roche Elecsys HIV combi PT & Duo assays to establish if this shift was observed across any other peer group.

FINDINGS

Below are the full listing of charts included in the investigation:

- Figure 1 – Participant 17 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 2 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by participant.
- Figure 3 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 4 – Participant 12 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 5 – Participant 13 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 6 – Participant 18 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 7 – Participant 57 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 8 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 9 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.
- Figure 10 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176 & DM22200, by reagent lot.
- Figure 11 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by participant.
- Figure 12 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.
- Figure 13 – Participant 1615 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.

- Figure 14 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag HT Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 15 – Peer group data for Abbott Alinity s HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 16 – Peer group data for Abbott Alinity i HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 17 – Peer group data for Abbott ARCHITECT HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 18 – Peer group data for bioMerieux VIDAS HIV DUO Ultra Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 19 – Peer group data for Bio-Rad Access HIV combo V2 Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 20 – Peer group data for Bio-Rad Genscreen HIV-1 Ag EIA (37C INC) Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Figure 21 – Peer group data for Bio-Rad Genscreen HIV-1 Ag EIA (40C INC) Assay, Optitrol HIVp24 DM22200, by reagent lot.
- Attachment 1 – DiaSorin COA documentation for reagent lot 139051
- Attachment 2 – DiaSorin COA documentation for reagent lot 139054
- Attachment 3 – DiaSorin COA documentation for reagent lot 139060 - 139057

DISCUSSION

All participant data reported to EDCNet for the peer group - DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200 - were investigated to establish whether there was any evidence of trends or patterns across the entire peer group. All other peer groups that reporting data for Optitrol HIVp24 DM22200 were also investigated to establish if the negative data was observed on any other platform / assay.

Figure 1 shows data from Participant 17 for Optitrol HIVp24 lot DM22200 when tested on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay. Three reagent lots were in use - 139051, 139054 and 139057. All data reported under reagent lot 139051 were within both assay and QConnect Limits, respectively. All data reported under reagent lots 139054 and 139057 were reported below both the assay and QConnect lower limit (S/Co 1.00).

Figures 2 and 3 show data for the peer group for Optitrol HIVp24 lot DM22200 when tested on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay by participant and reagent lot, respectively. Data reported by the peer group across all three reagent lots in use for Participant 17 were consistent with S/Co values reported by Participant 17. All data reported for reagent lots 139054 and 139057 were reported below S/Co 1.00.

Figures 4 – 8 show data for each participant (12, 13, 18, 57 & 1425) testing with Optitrol HIVp24 DM22200 on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay. Three participants, 13, 57 and 1425, reported data for reagent lot 139054, these data were consistent with data reported by Participant 17, below S/Co 1.00 (figures 5, 7 and 8). No other participant had reported data for reagent lot 139057 and all participant data reported for other reagent lots in use (139050, 139051 and 139053) were reported within both assay and QConnect Limits.

Figure 9 shows data for Participant 1425 testing with Optitrol HIVp24 DM21176 on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay. Optitrol HIVp24 DM21176 was the lot released prior to Optitrol HIVp24 DM22200. Three reagent lots were in use, 139050, 139053 and 139054. All data reported for 139054 were reported below both the assay and QConnect Limits (S/Co 1.00), consistent with data reported for Optitrol HIVp24 DM22200. All data reported under the remaining reagent lots was reported within both assay and QConnect Limits.

Figures 11 and 12 show peer group data for Optitrol HIVp24 DM21176 on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay by participant and reagent lot respectively. Three participants, 1425, 1615 and 57, reported data below both the assay and QConnect Limits. After investigating Participant 57 data, the single data point reported below the lower limit on reagent lot 139052 was an invalid data point due to instrument error as noted by the participant at time of data entry.

Figure 13 shows Participant 1615 data for the for Optitrol HIVp24 DM21176 on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay by reagent lot. Data was reported for five reagent lots, 139051, 139052, 139053, 139054 and 139056, with data reported below the assay and QConnect Limits for 139052, 139054 and 139056. Further investigation into the negative data reported for reagent lot 139052 showed data was invalid as reported by the participant at data entry. Negative data reported for reagent lots 139054 and 139056 were consistent with that reported for Optitrol HIVp24 DM22200.

Figures 14 – 21 show peer group data for all other platforms with assays reporting data for Optitrol HIVp24 DM22200, these include the DiaSorin LIAISON XL MUREX HIV Ab/Ag HT Assay, Abbott Alinity s and i HIV Ag/Ab Combo Assays, Abbott ARCHITECT HIV Ag/Ab Combo Assay, bioMerieux VIDAS HIV DUO Ultra Assay, Bio-Rad Access HIV combo V2 Assay and the Bio-Rad Genscreen HIV-1 Ag EIA (37C & 47C) assays.

No data were reported below the lower assay or QConnect Limits for any of the above assays when testing with Optitrol HIVp24 DM22200 and no negative shift was observed.

The negative data reported by Participant 17 for Optitrol HIVp24 DM22200 when testing on DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay with reagent lots 139054 and 139057 were observed across the peer group. This shift was also observed on data reported for Optitrol HIVp24 DM21176 when tested with reagent lots 139054 and 139056.

NRL contacted DiaSorin for information regarding any change in the manufacturer or production of the affected lots. DiaSorin has provided NRL with the COA reports for reagent lots 139051, 139054 and 310260-139057 for review with DiaMex for further investigation. (Attachments 1, 2 and 3).

RECOMMENDATIONS

NRL recommends working with DiaMex and DiaSorin to further investigate the negative shift observed on the DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay for reagent lots 139054, 139056 and 139057. It is unclear whether clinical sensitivity for HIVp24 antigen has been affected in these specific reagent lots and this is for DiaSorin to determine.

NRL recommends that participants ensure calibrations and DiaSorin kit controls are valid and within range, and that the instrument is maintained as per DiaSorin protocol.

NRL recommends that Participants review their data in comparison to peer group data.

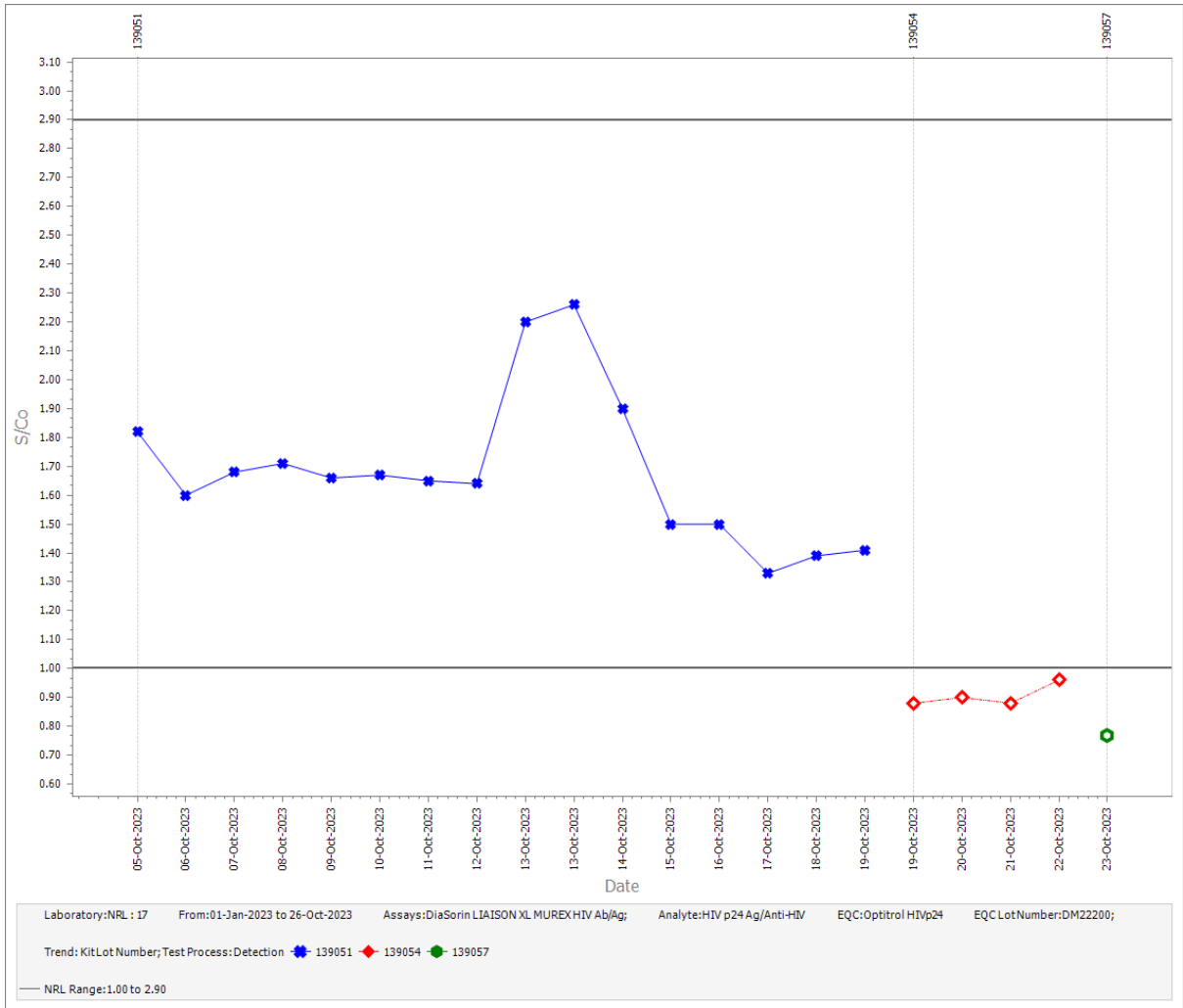


Figure 1 – Participant 17 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIV/p24 DM22200, by reagent lot.

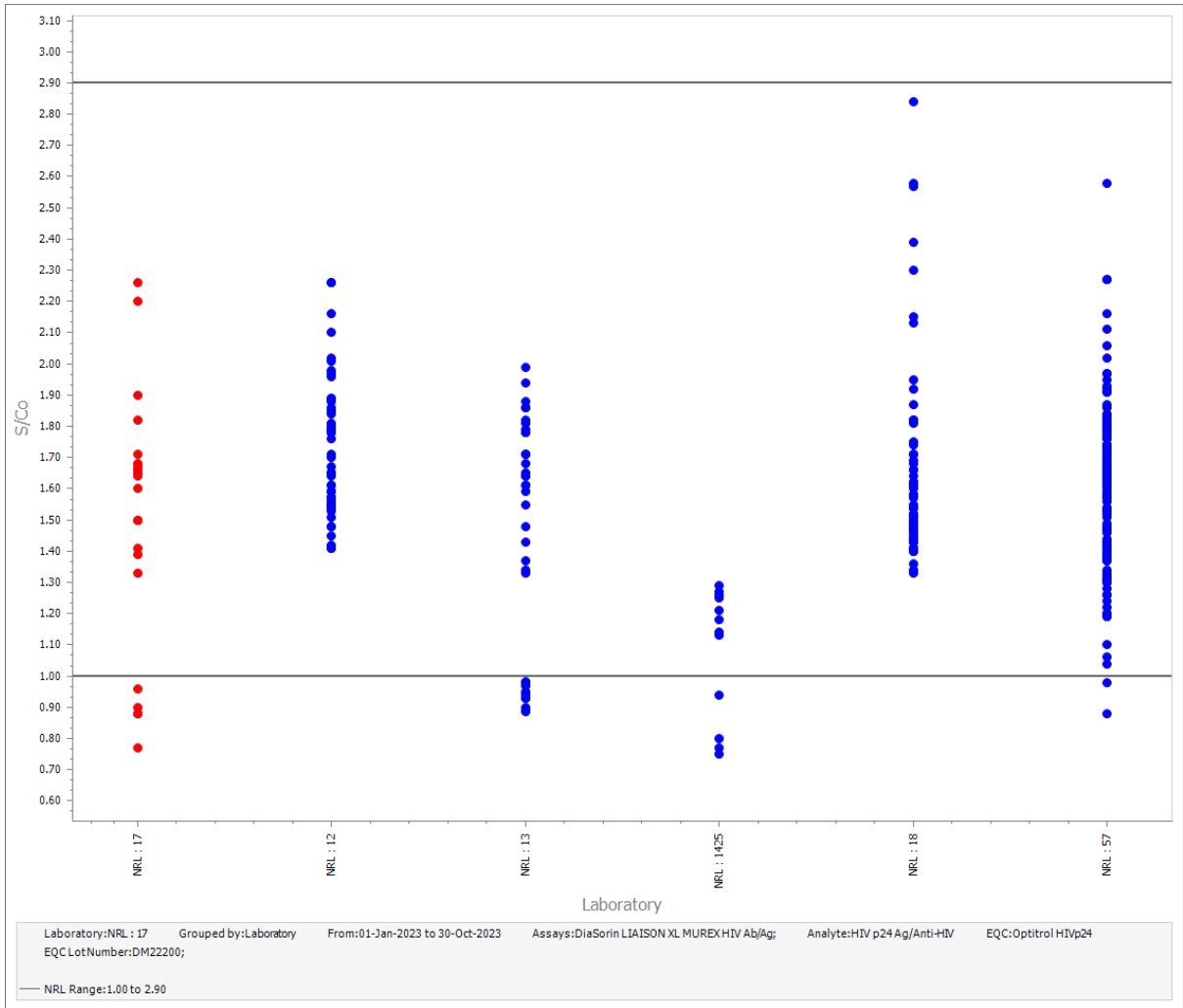


Figure 2 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by participant.

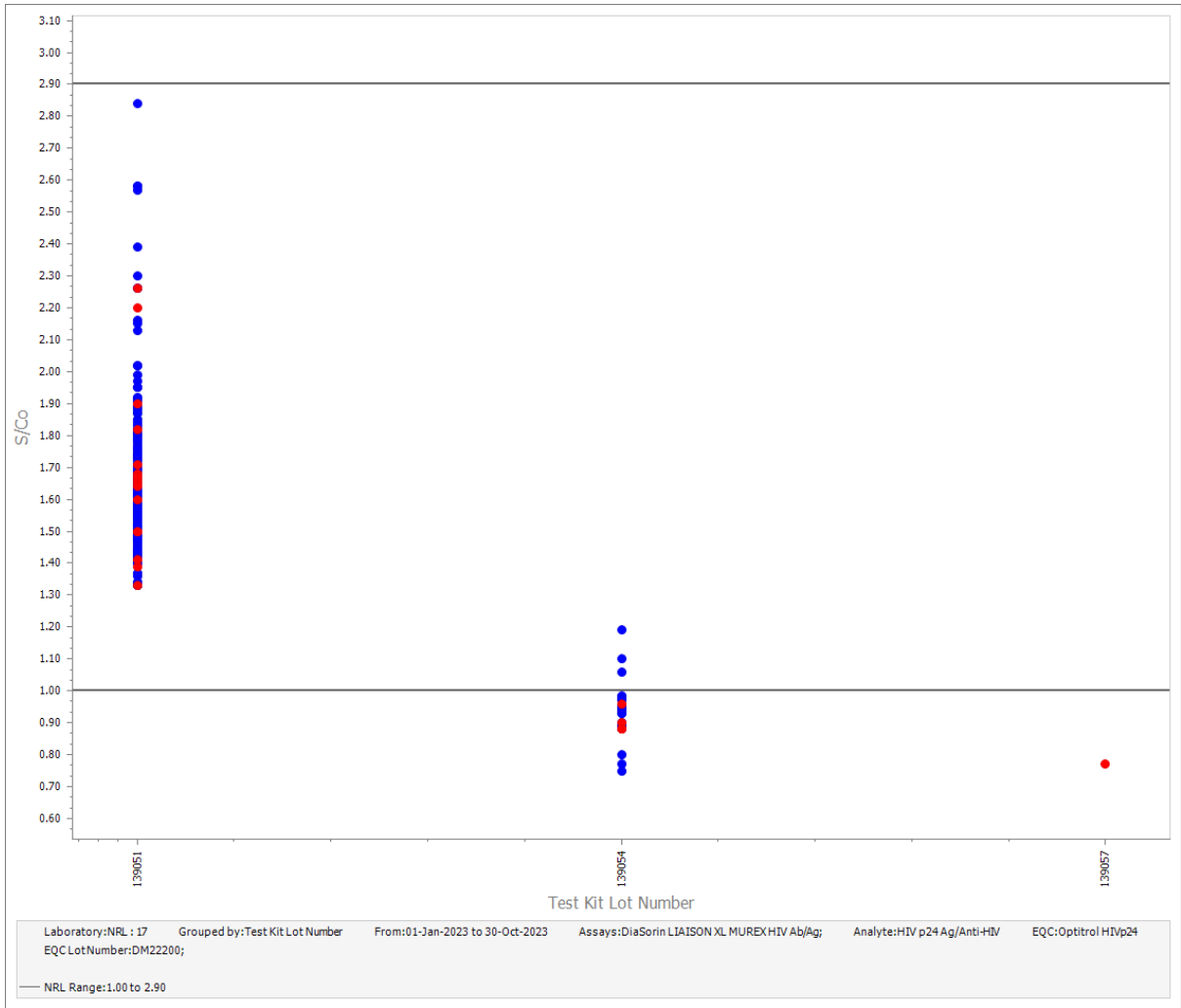


Figure 3 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.

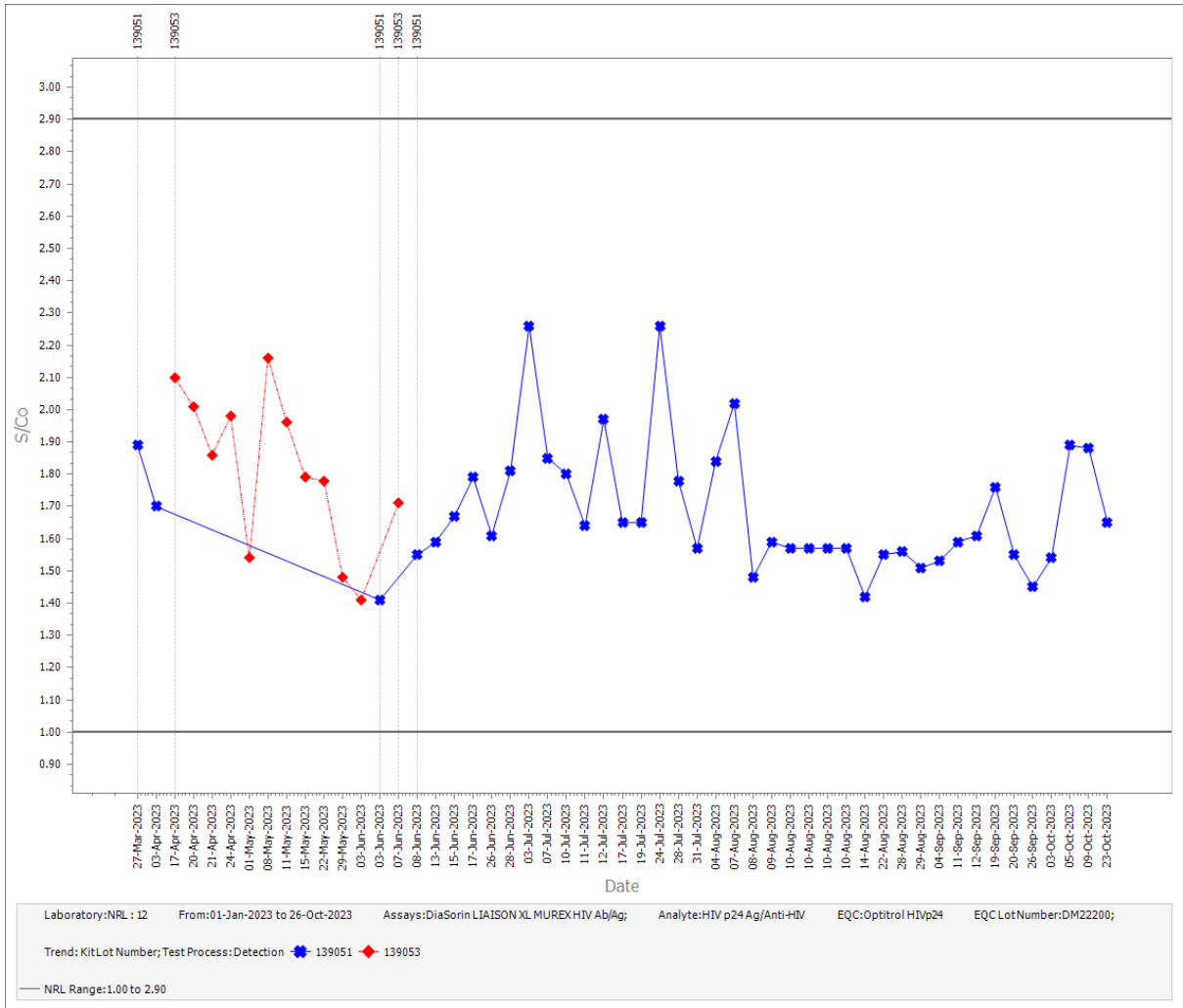


Figure 4 – Participant 12 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.

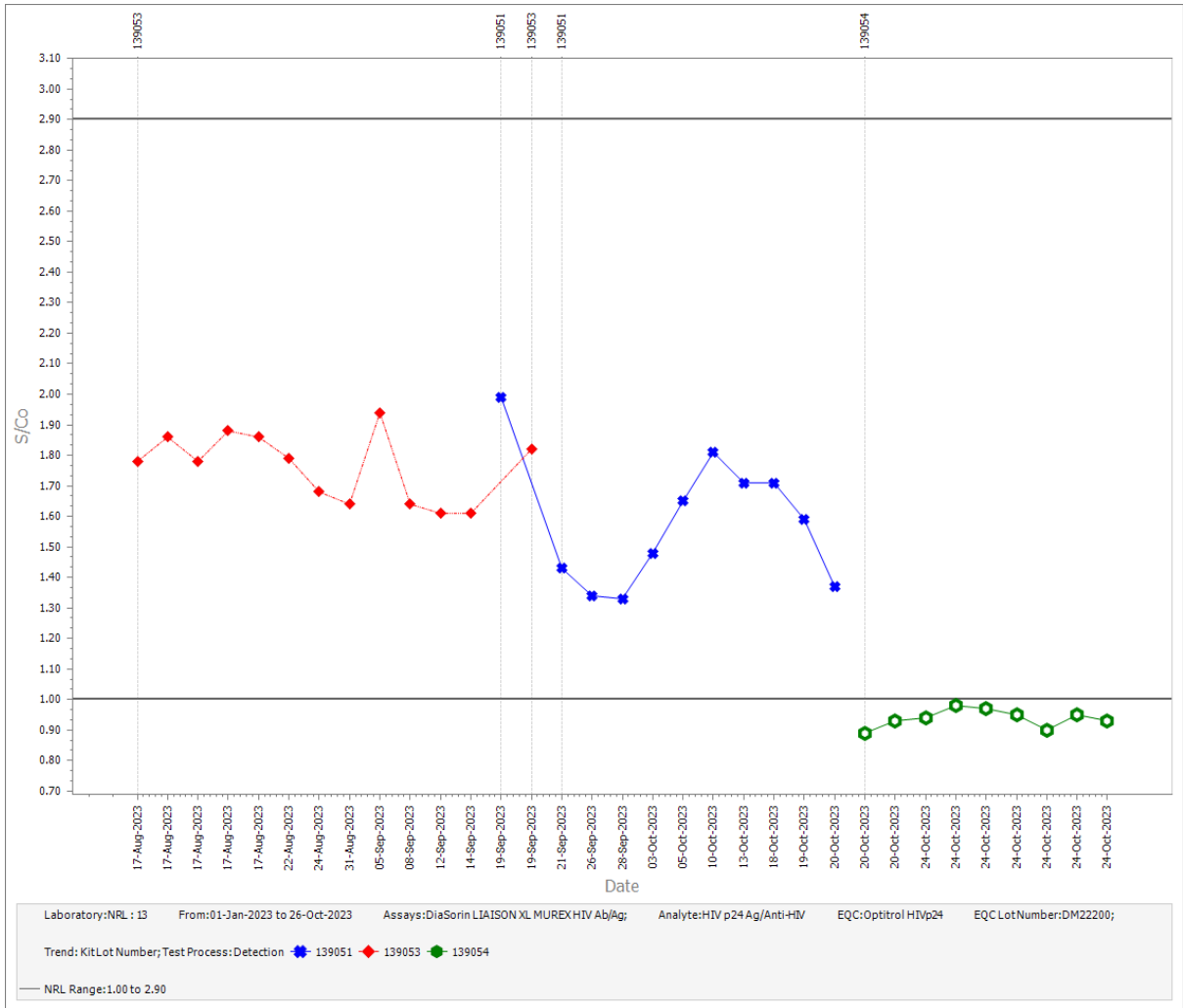


Figure 5 – Participant 13 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIV/p24 DM22200, by reagent lot.

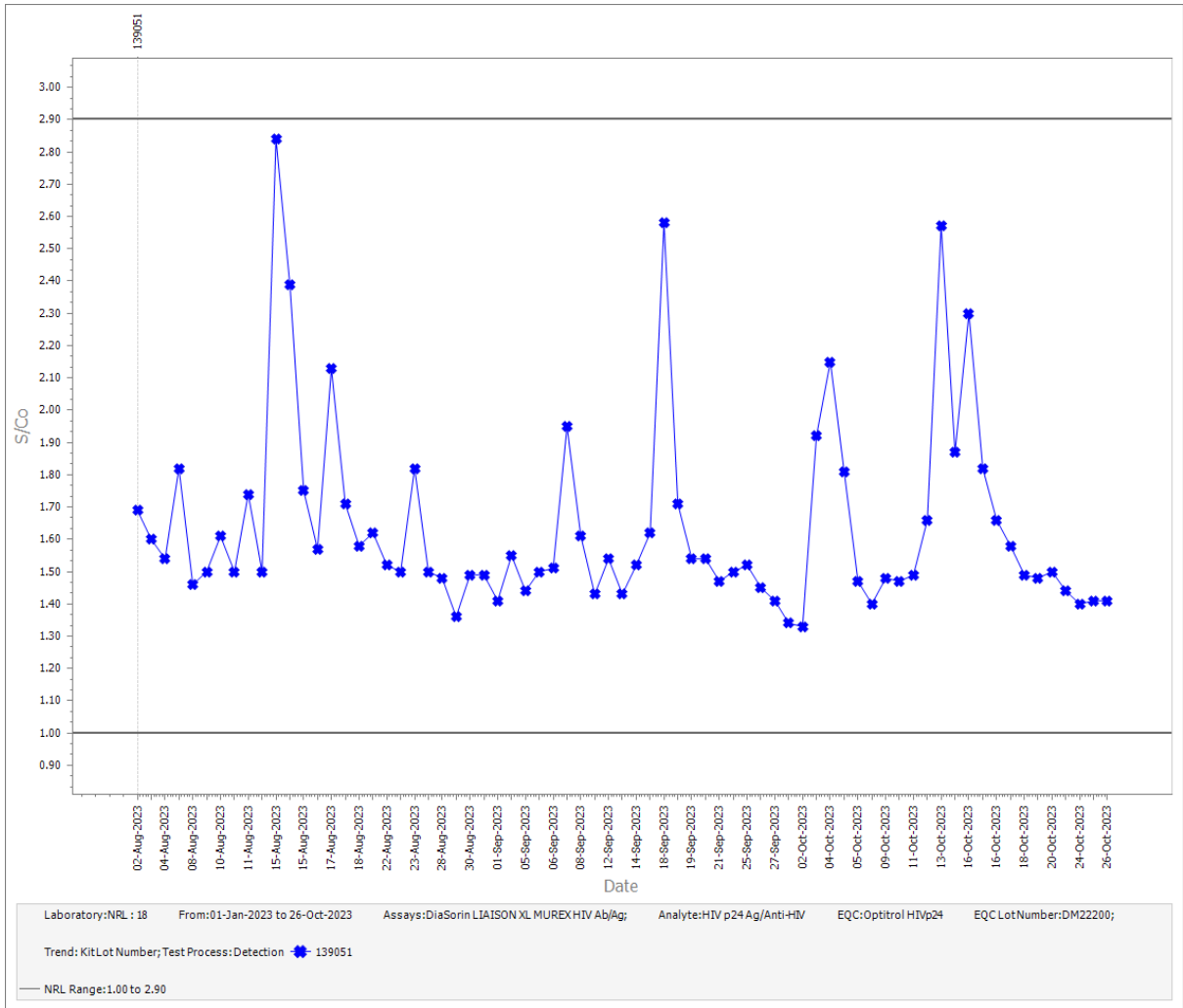


Figure 6 – Participant 18 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.

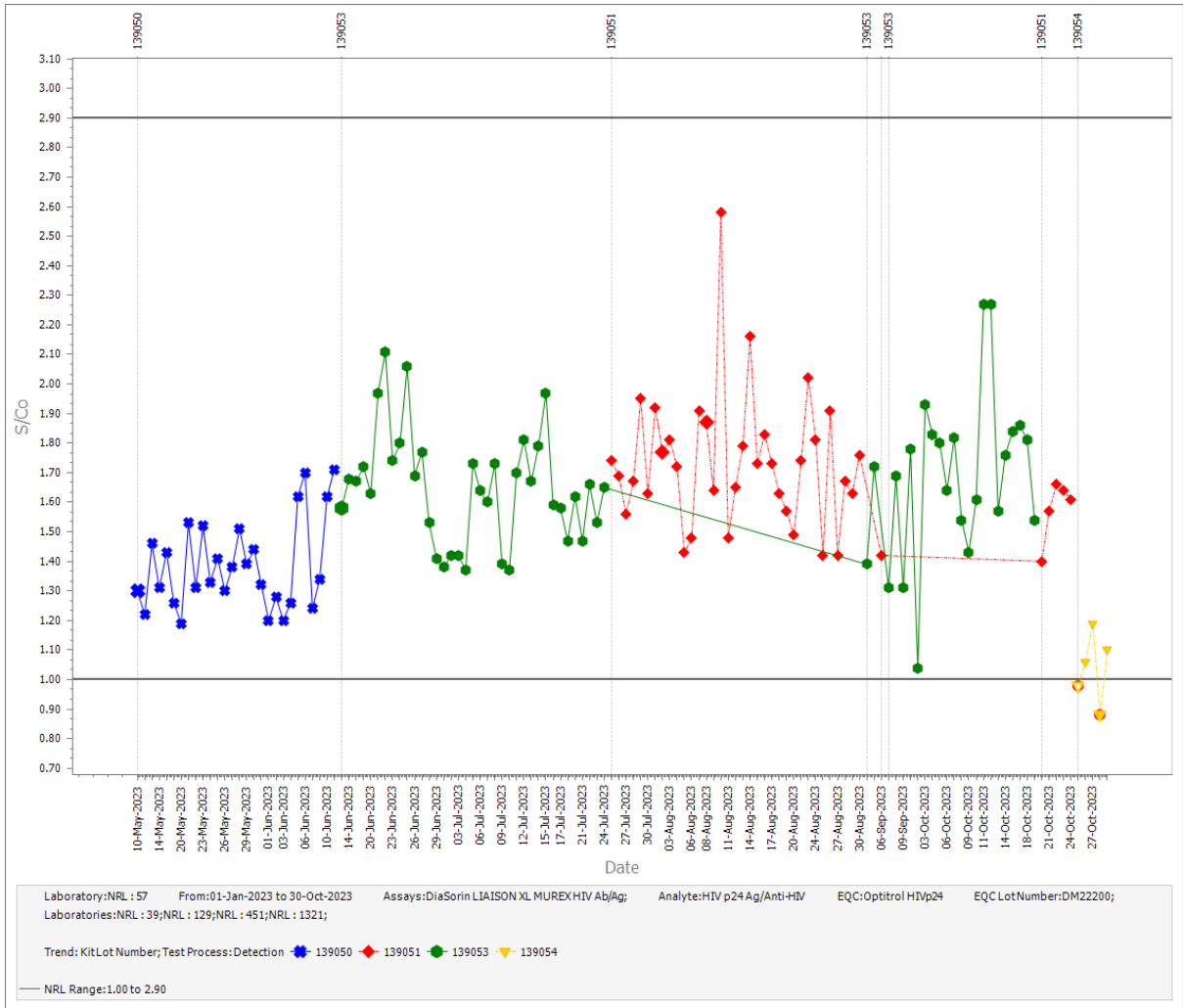


Figure 7 – Participant 57 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.

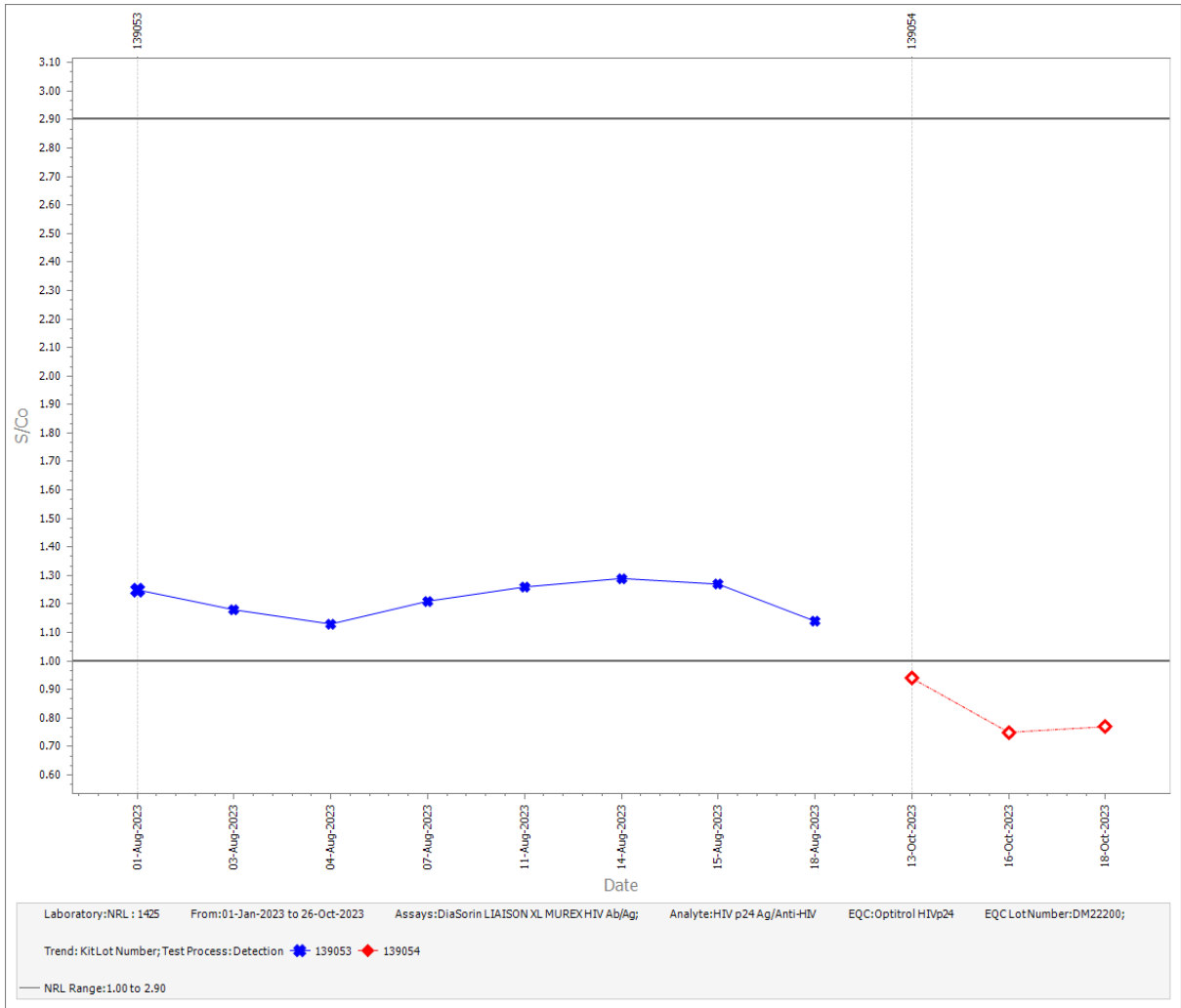


Figure 8 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM22200, by reagent lot.

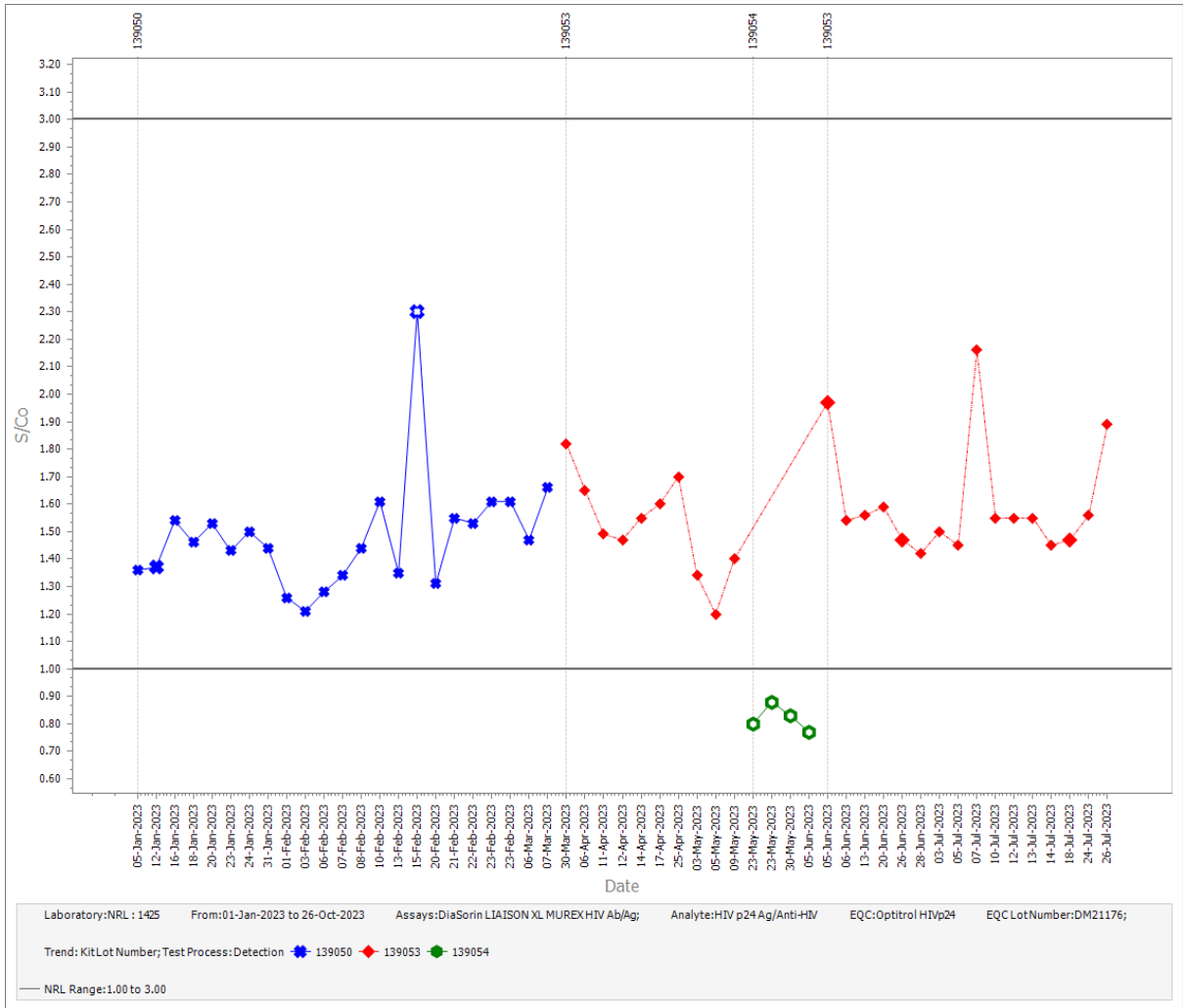


Figure 9 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.

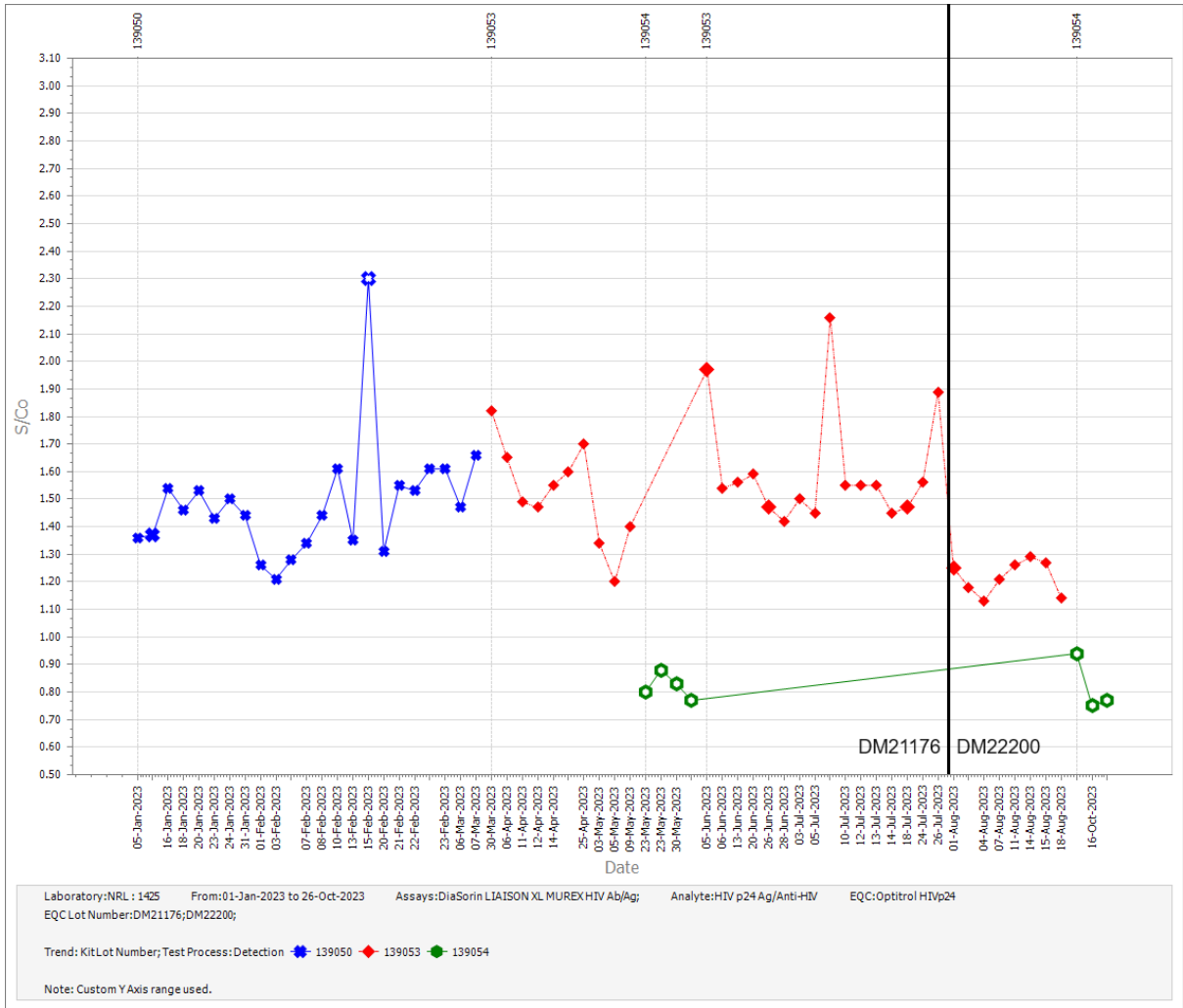


Figure 10 – Participant 1425 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176 & DM22200, by reagent lot.

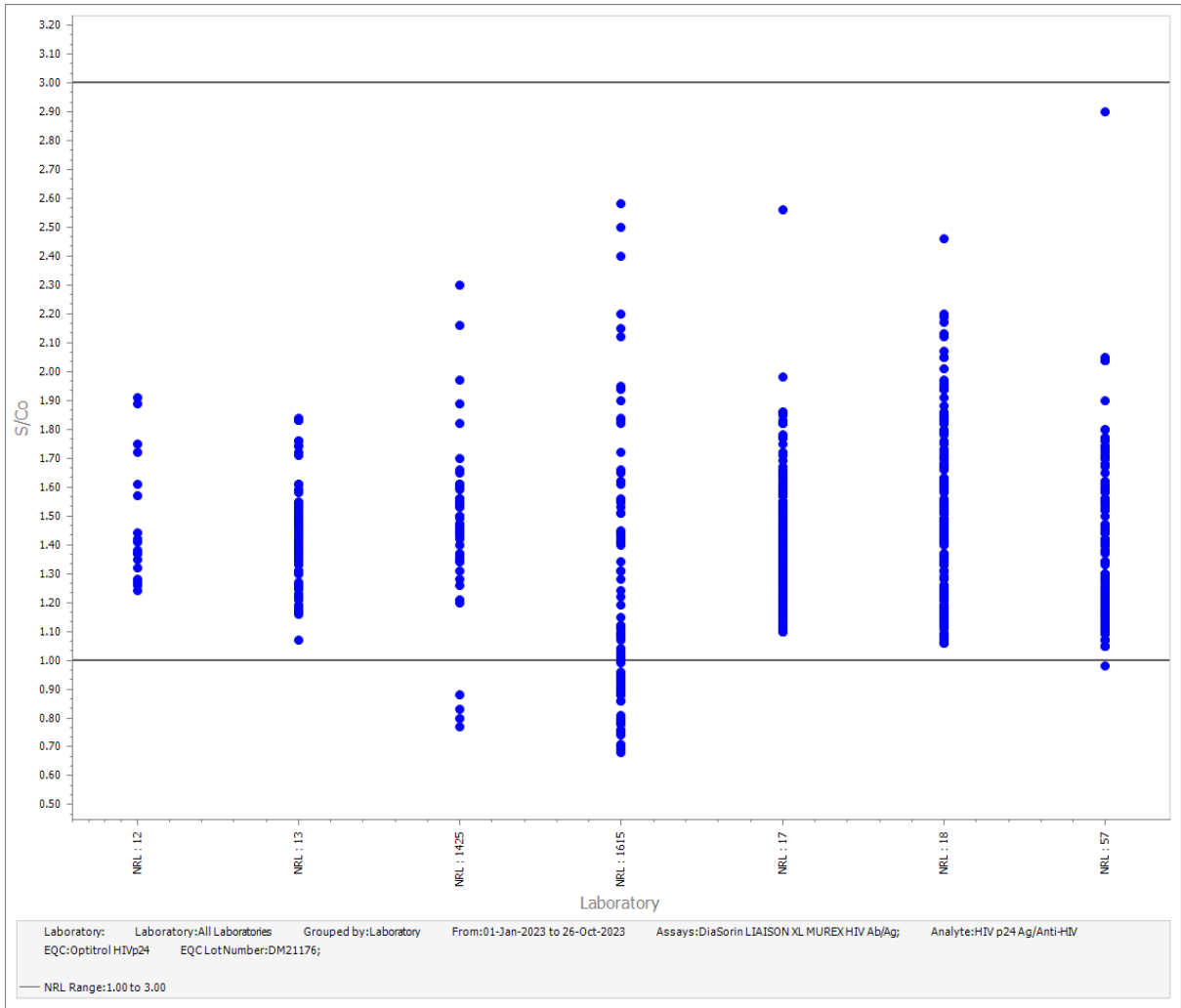


Figure 11 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by participant.

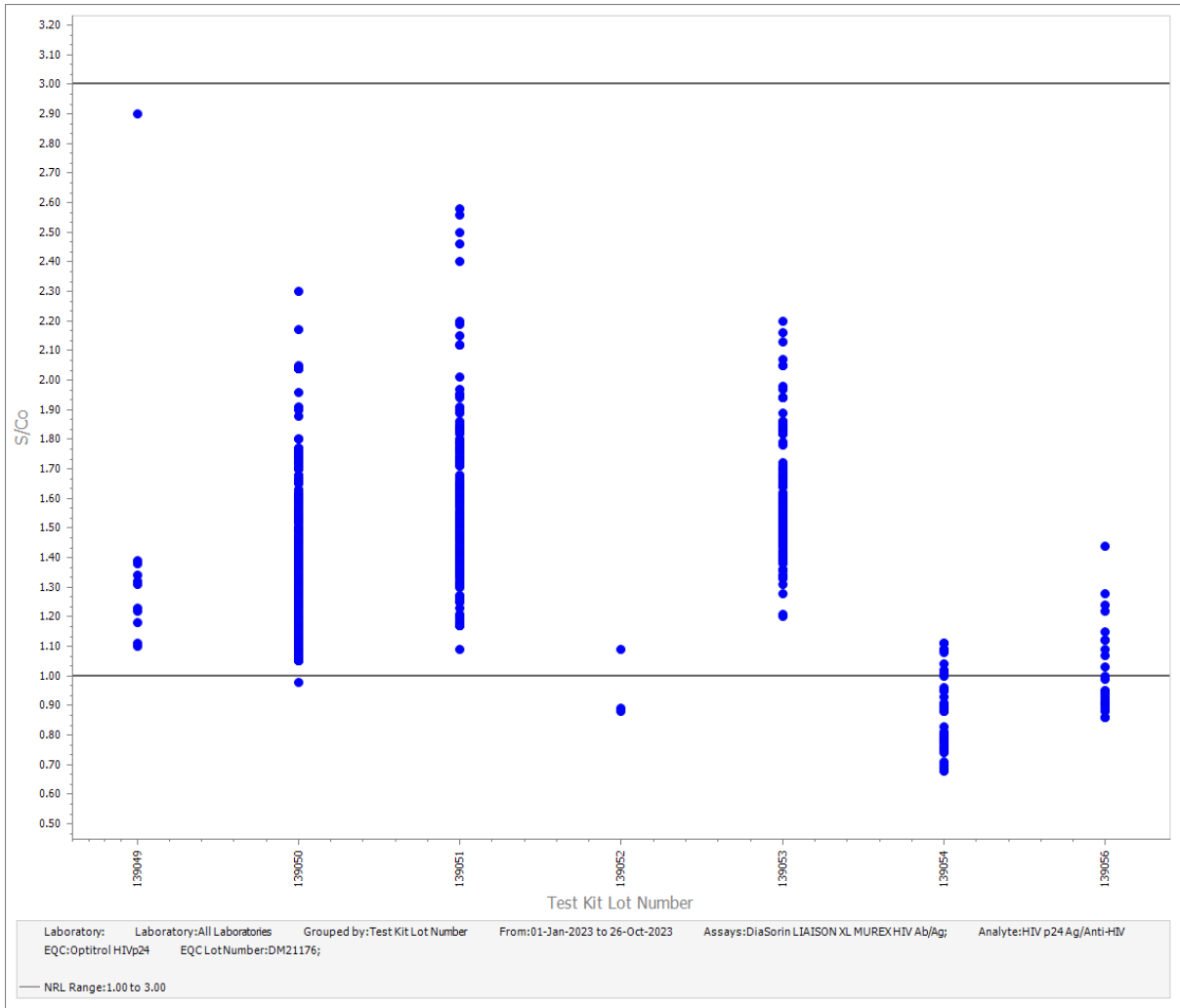


Figure 12 – Peer group data for DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.

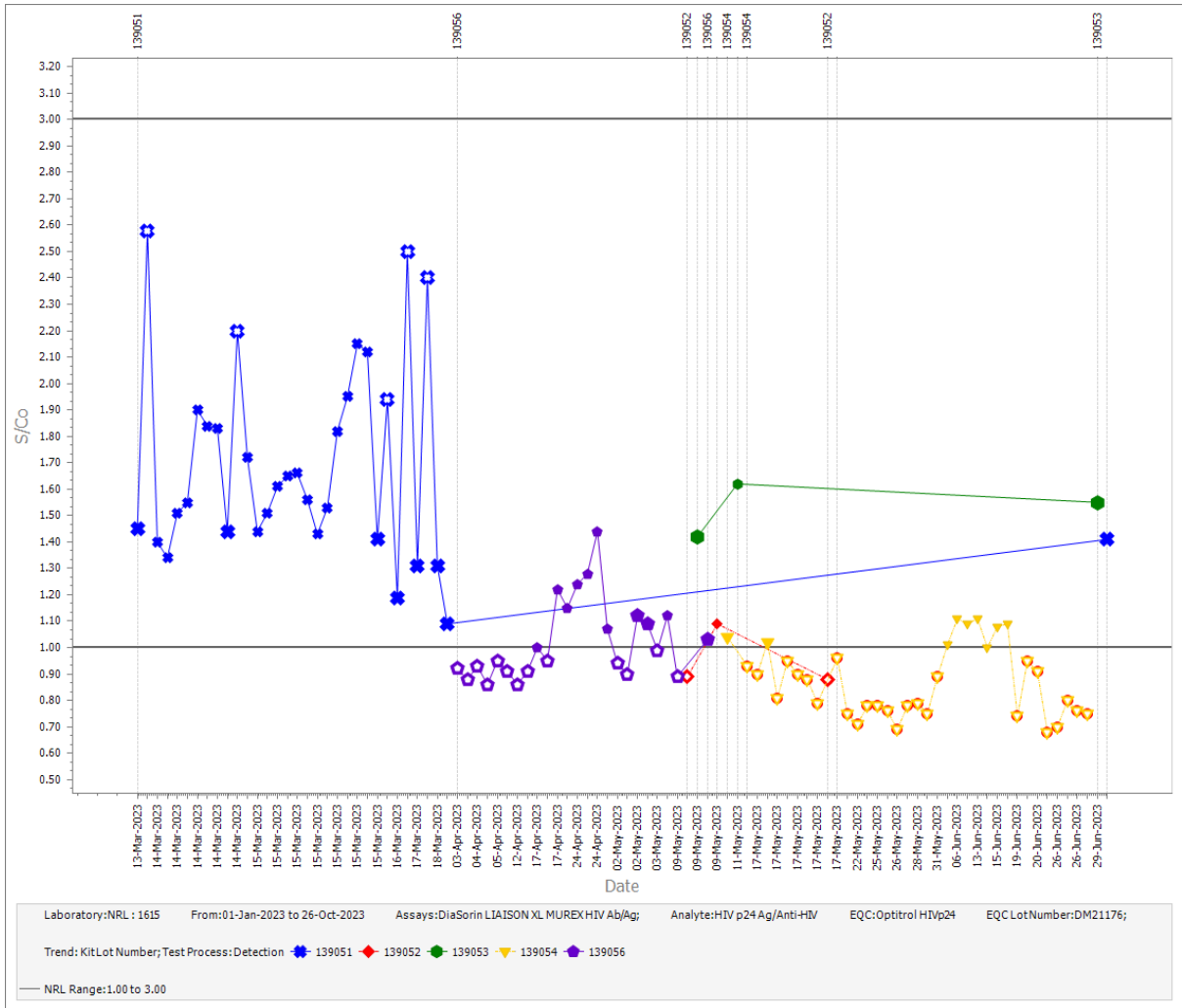


Figure 13 – Participant 1615 DiaSorin LIAISON XL MUREX HIV Ab/Ag Assay, Optitrol HIVp24 DM21176, by reagent lot.

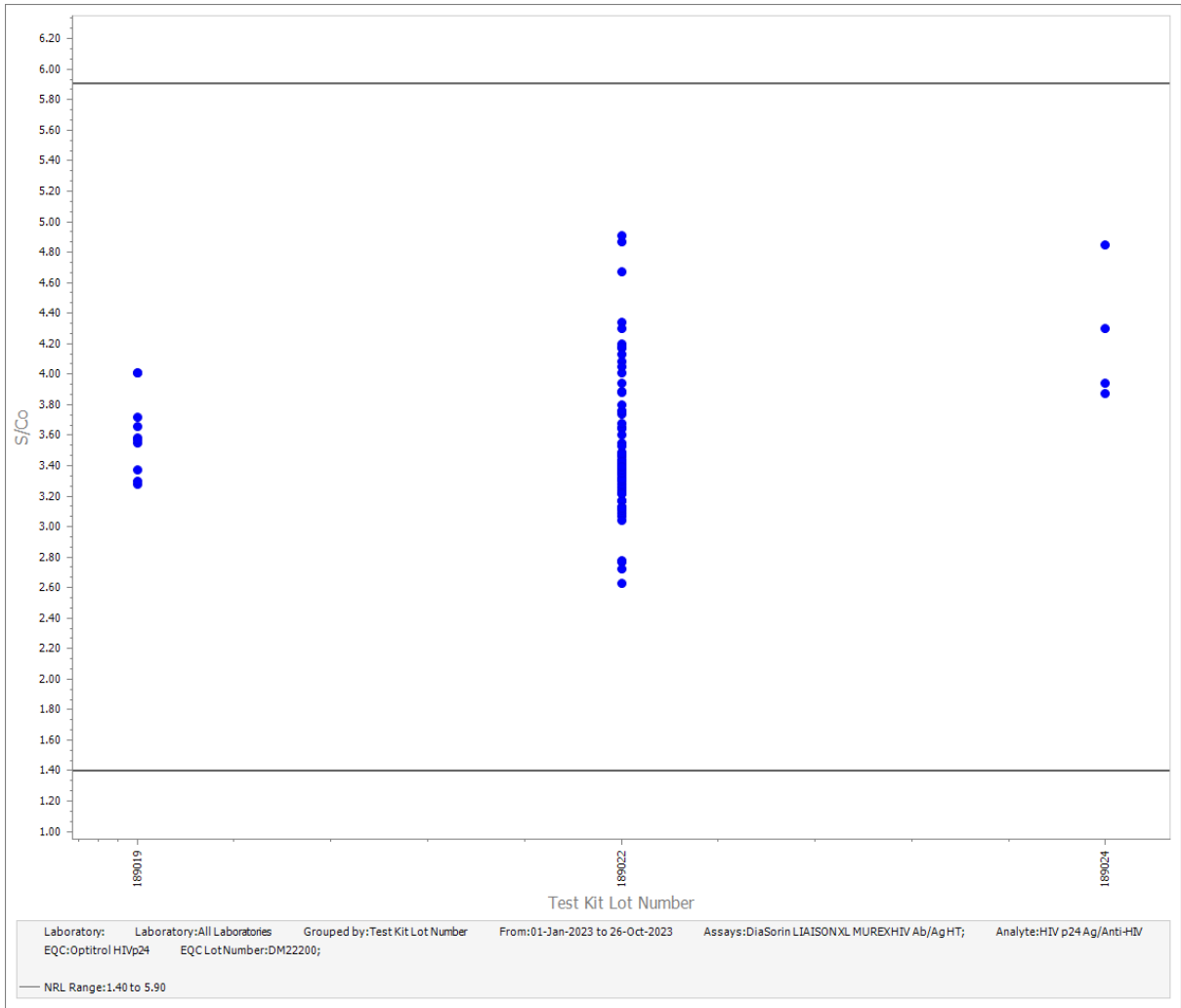


Figure 14 – Peer group data for Optitrol HIVp24 DM22200 when tested on the DiaSorin LIAISON XL MUREX HIV Ab/Ag HT, by reagent lot.

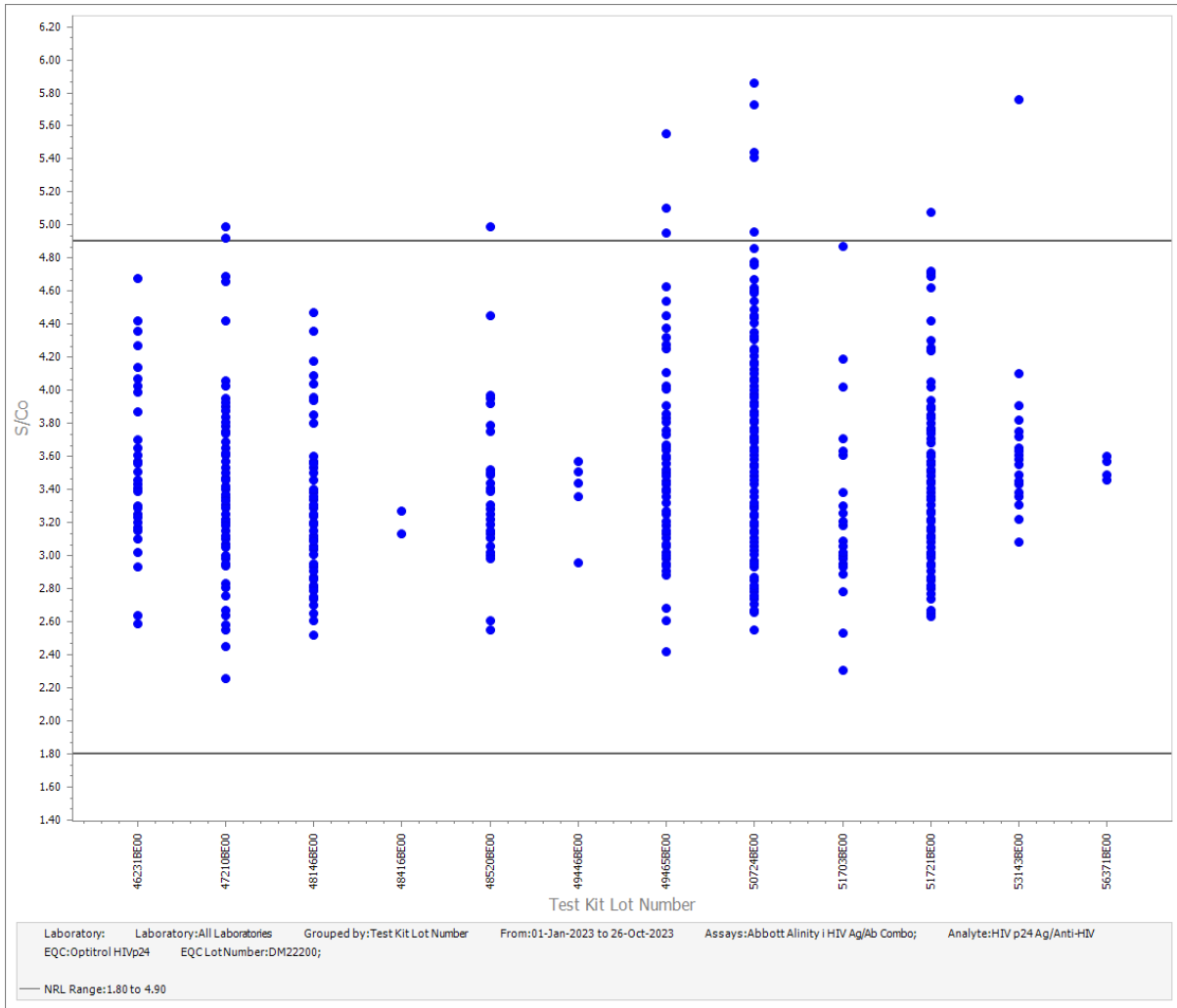


Figure 15 – Peer group data for Abbott Alinity i HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM21176, by reagent lot.

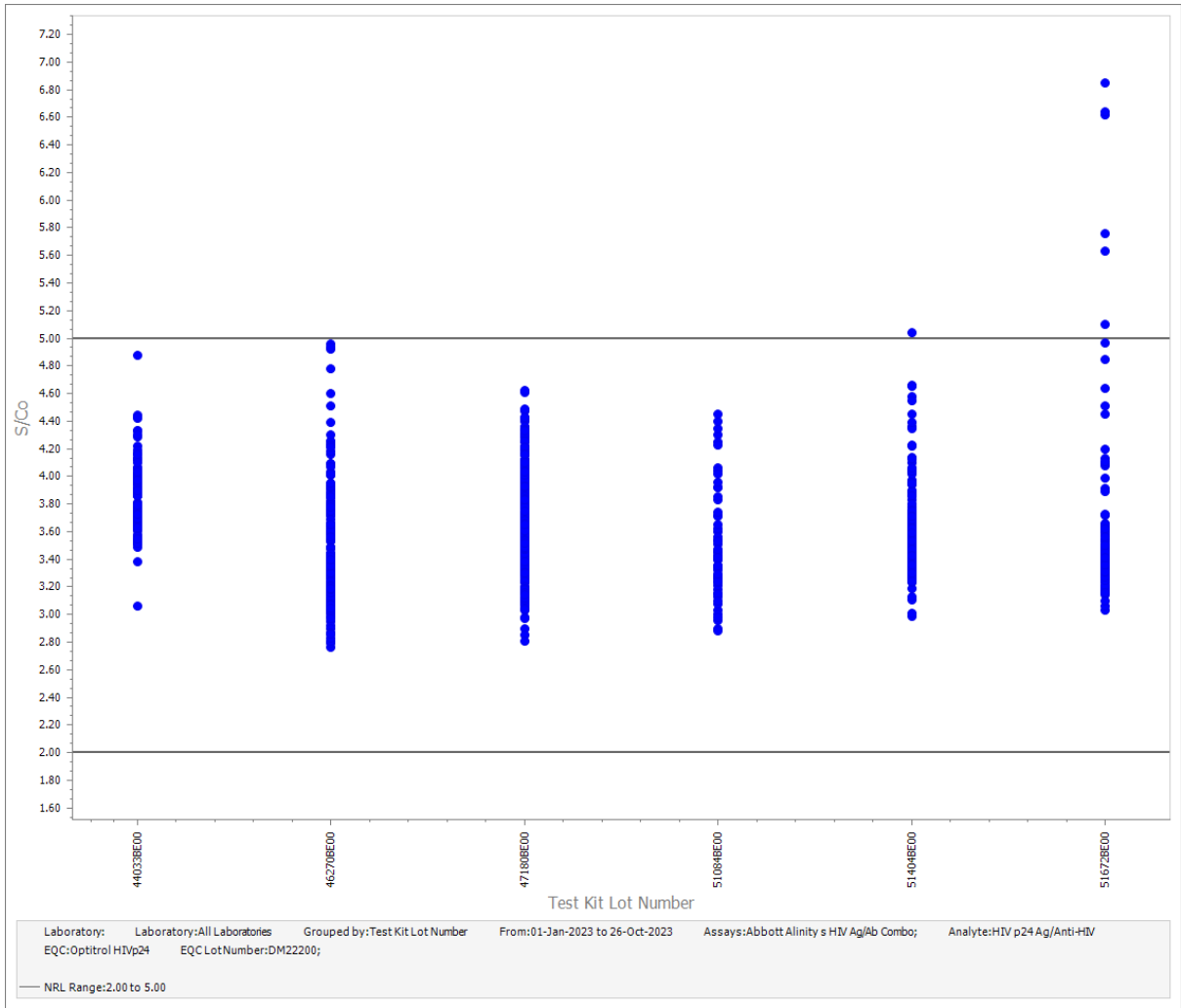


Figure 16 – Peer group data for Abbott Alinity s HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM21176, by reagent lot.

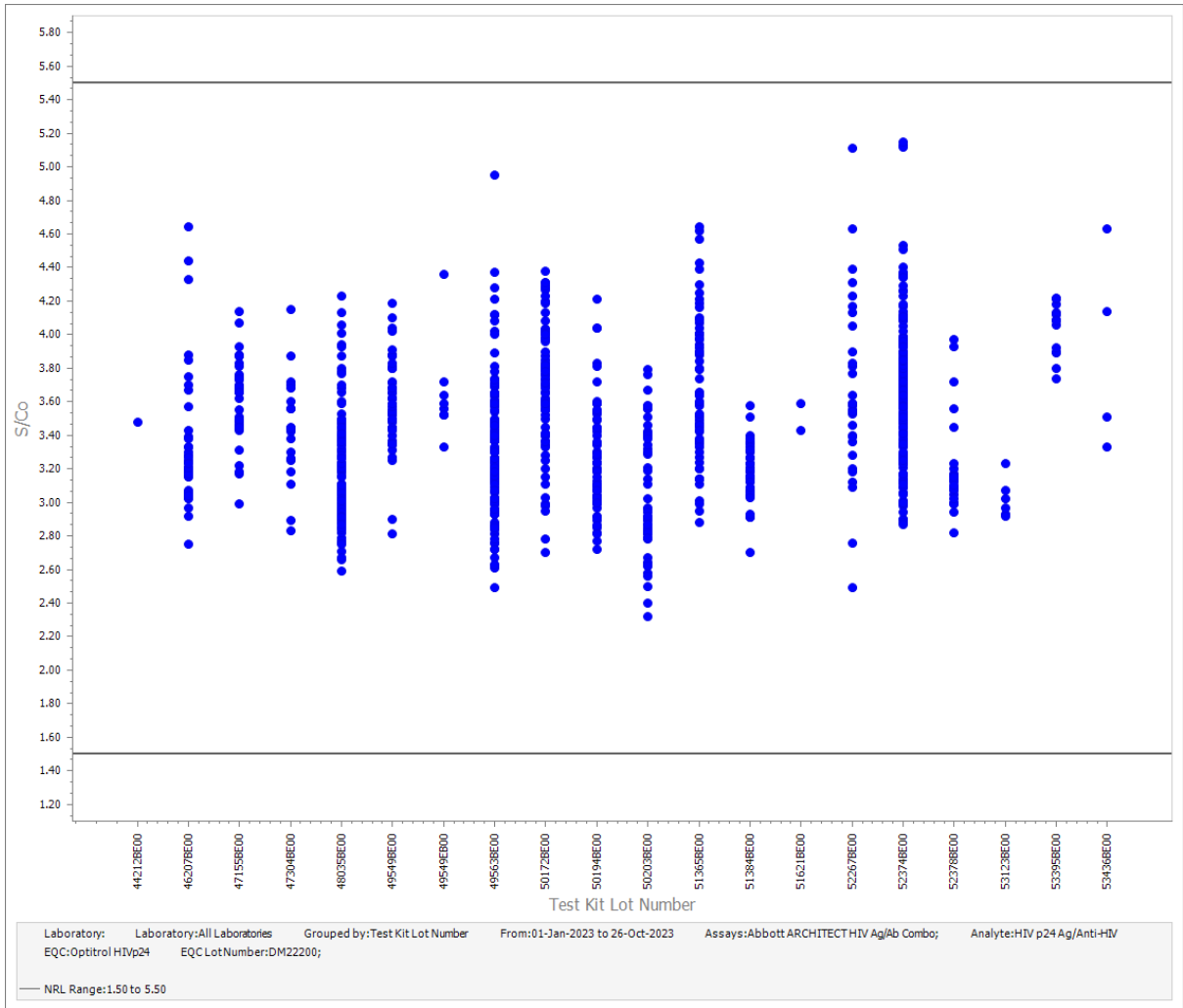


Figure 17 – Peer group data for Abbott ARCHITECT HIV Ag/Ab Combo Assay, Optitrol HIVp24 DM21176, by reagent lot.

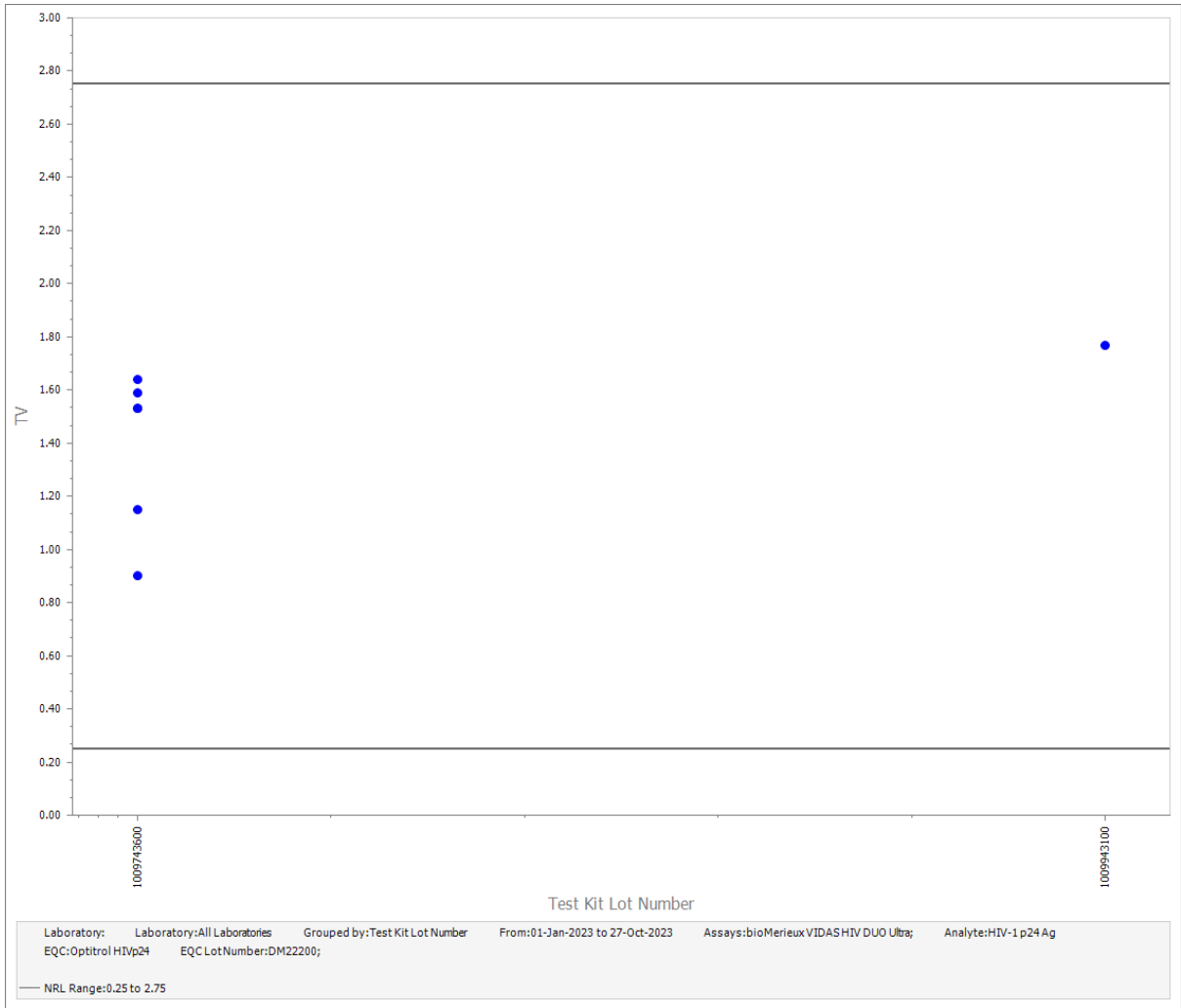


Figure 18 – Peer group data for bioMerieux VIDAS HIV DUO Ultra Assay, Optitrol HIVp24 DM22200, by reagent lot.

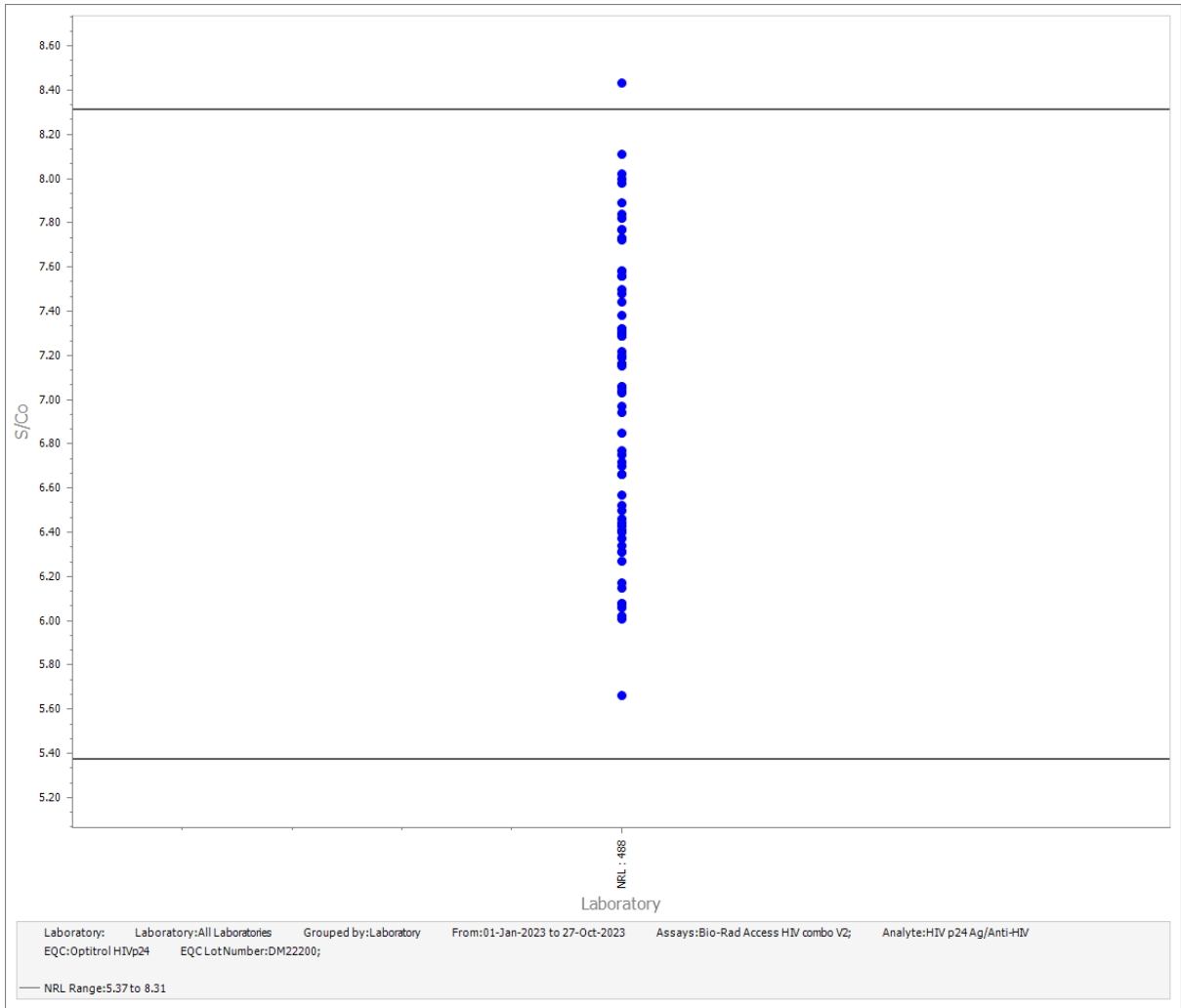


Figure 19 – Peer group data for Bio-Rad Access HIV combo V2 Assay, Optitrol HIVp24 DM22200, by reagent lot.

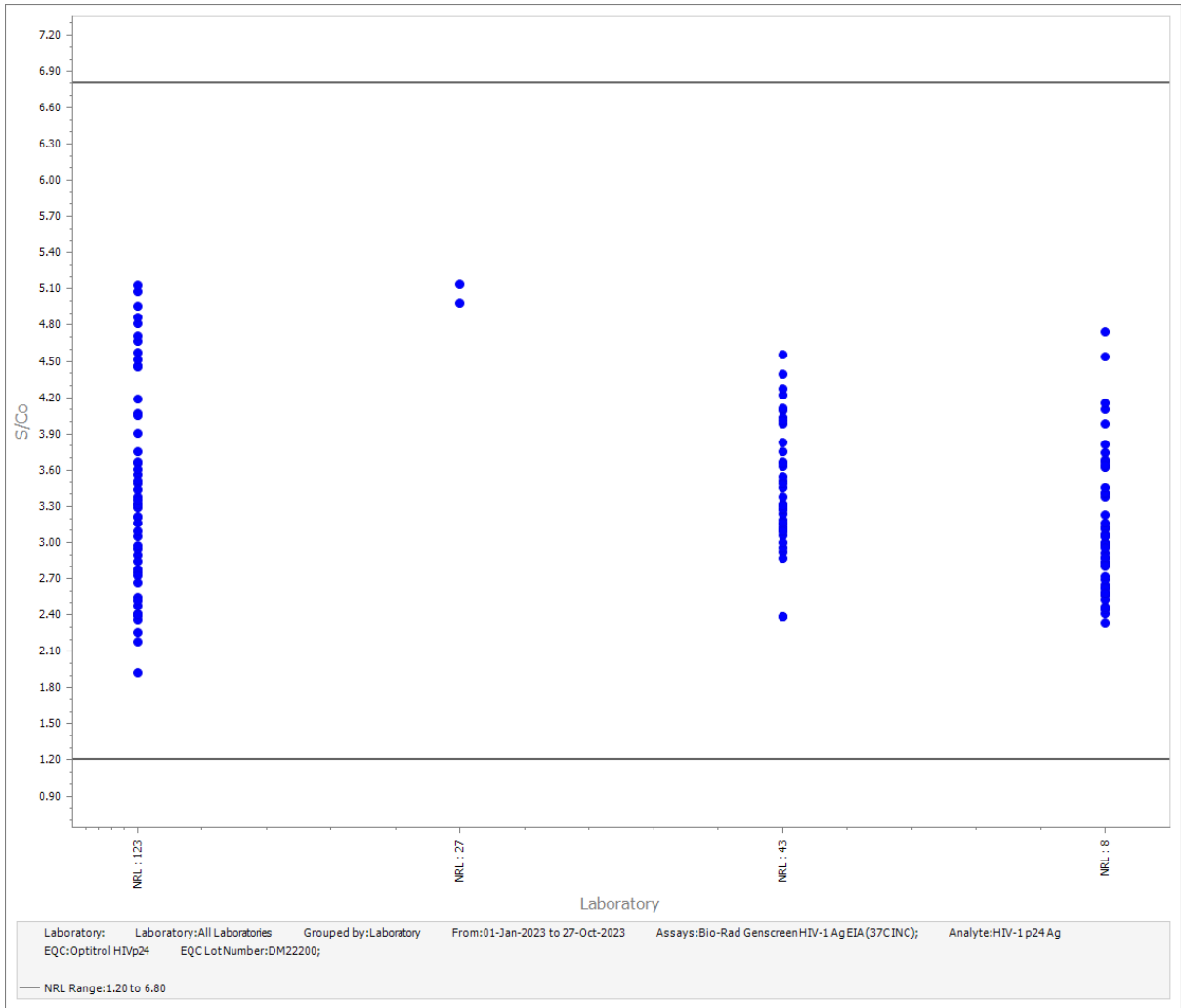


Figure 20 – Peer group data for Bio-Rad Genscreen HIV-1 Ag EIA (37C INC) Assay, Optitrol HIVp24 DM22200, by reagent lot.

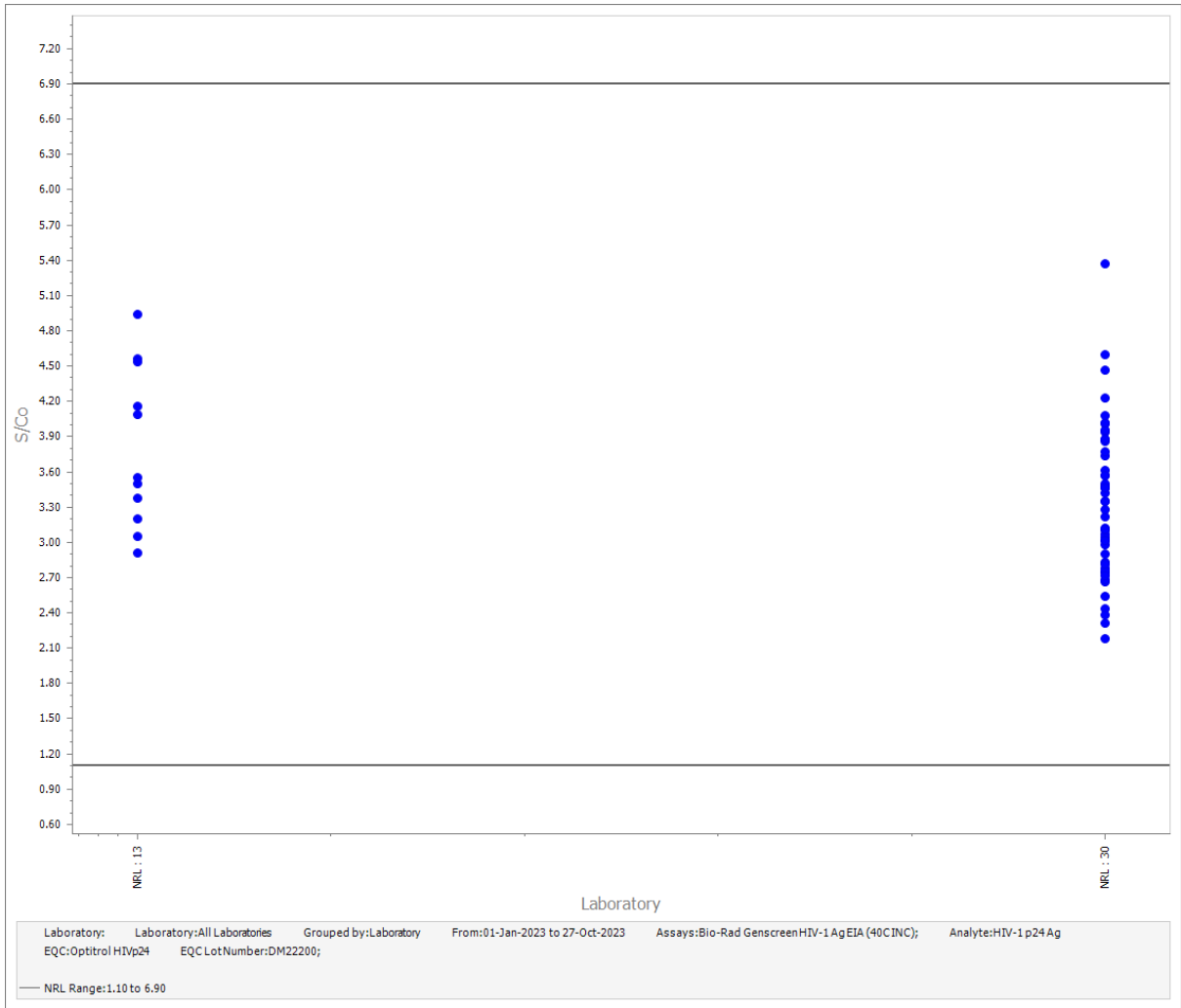


Figure 21 – Peer group data for Bio-Rad Genscreen HIV-1 Ag EIA (40C INC) Assay, Optitrol HIVp24 DM22200, by reagent lot.

Attachment 1 – DiaSorin COA documentation for reagent lot 139051

Attachment 2 – DiaSorin COA documentation for reagent lot 139054

Attachment 3 – DiaSorin COA documentation for reagent lot 139060 - 139057