

QC SEROLOGY INVESTIGATION PMM-QC-981

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INTRODUCTION

During daily review of out of range (OOR) data submitted to EDCNet, a number of data were reported by multiple participants within the peer group as S/Co <1.00 for Optitrol Red QC lots DM20156 and DM21157 when testing with the Bio-Rad MONOLISA HBsAg ULTRA assay reagent lot 1K0709.

FINDINGS

- Figure 1 – Peer group data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by participant.
- Figure 2 – Peer group data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.
- Figure 3 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.
- Figure 4 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.
- Figure 5 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.
- Figure 6 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.
- Figure 7 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.
- Figure 8 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.
- Figure 9 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.
- Figure 10 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.
- Figure 11 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.
- Figure 12 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM21157 by reagent lot.
- Figure 13 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.
- Figure 14 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.

DISCUSSION

When investigating these unexpected QC data entered as S/Co <1.00 when testing with the Bio-Rad MONOLISA HBsAg ULTRA assay reagent lot 1K0709, all data (including positive and negative kit controls) from participants in the peer group were included to establish whether there was any evidence of trends or patterns across the peer group or reagent lots in use.

Figures 1 and 2 show peer group data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Red DM20156 and DM21157 by Participant and reagent lot consecutively. Data below S/Co 1.00 were identified for both Optitrol Red QC lots in use with reagent lot 1K0709.

Figures 3, 4 and 5 show Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM20156 and DM21157, positive and negative kit controls by reagent lot. There were no data entered as S/Co <1.00 observed for either of the kit controls and no shift down was identified.

Figures 6, 7 and 8 show Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay,

Optitrol Blue DM20156 and DM21157, positive and negative kit control by reagent lot. There were no data entered as S/Co <1.00 observed for either of the kit controls and no shift down was identified.

Figures 9, 10 and 11 show Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM20156 and DM21157, positive and negative kit controls by reagent lot. There were no data entered as S/Co <1.00 observed for either of the kit controls and no shift down was identified.

Figures 12, 13 and 14 show Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM21157, positive and negative kit controls by reagent lot. There were no data entered as S/Co <1.00 observed for either of the kit controls and no shift down was identified.

NRL contacted participants identified above, where data were reported as S/Co <1.00 for the Bio-Rad MONOLISA HBsAg ULTRA assay, to investigate if there were any common laboratory factors which could be identified as the cause of the variation. NRL received communication from the DiaMex distributor, Copernicus Diagnostics pl, informing NRL that following the initial NRL communication, participants contacted Bio-Rad Laboratories requesting an investigation into the issue. The participants received communication from Bio-Rad Laboratories, which was in turn communicated to NRL via Copernicus Diagnostics pl, that there was an issue with the conjugate for the 1K0709 series and these reagent lots would be replaced.

RECOMMENDATIONS

NRL to review and modify all data reported for the Bio-Rad MONOLISA HBsAg ULTRA assay reagent lot 1K0709 as invalid in EDCNet.

NRL recommends participants discontinue use of reagent lot 1K0709 for Bio-Rad MONOLISA HBsAg ULTRA assay and request replacement stock from Bio-Rad Laboratories.

NRL to continue to monitor all reagent lots for the Bio-Rad MONOLISA HBsAg ULTRA assay.

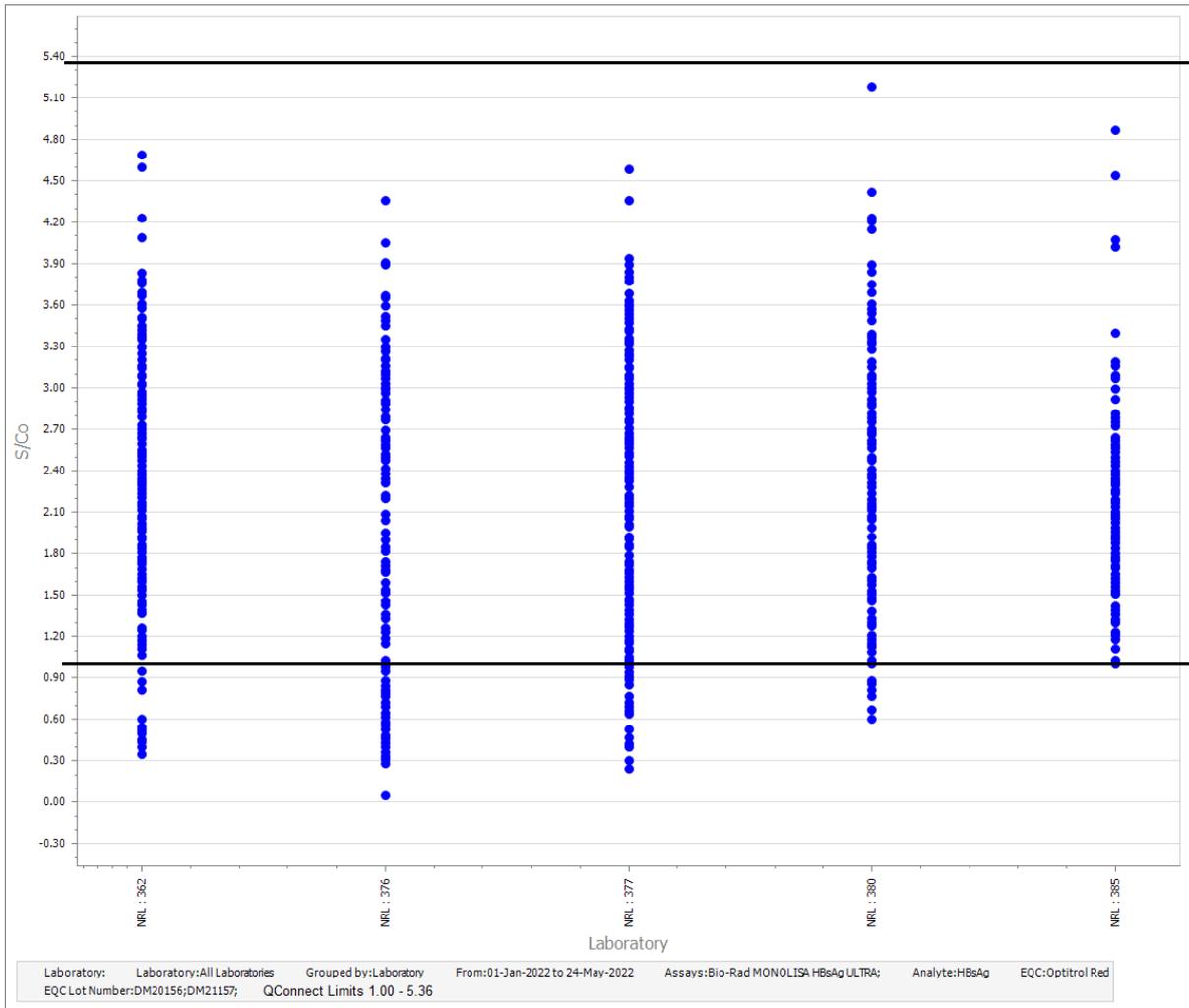


Figure 1 – Peer group data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM20156 and DM21157 by participant.

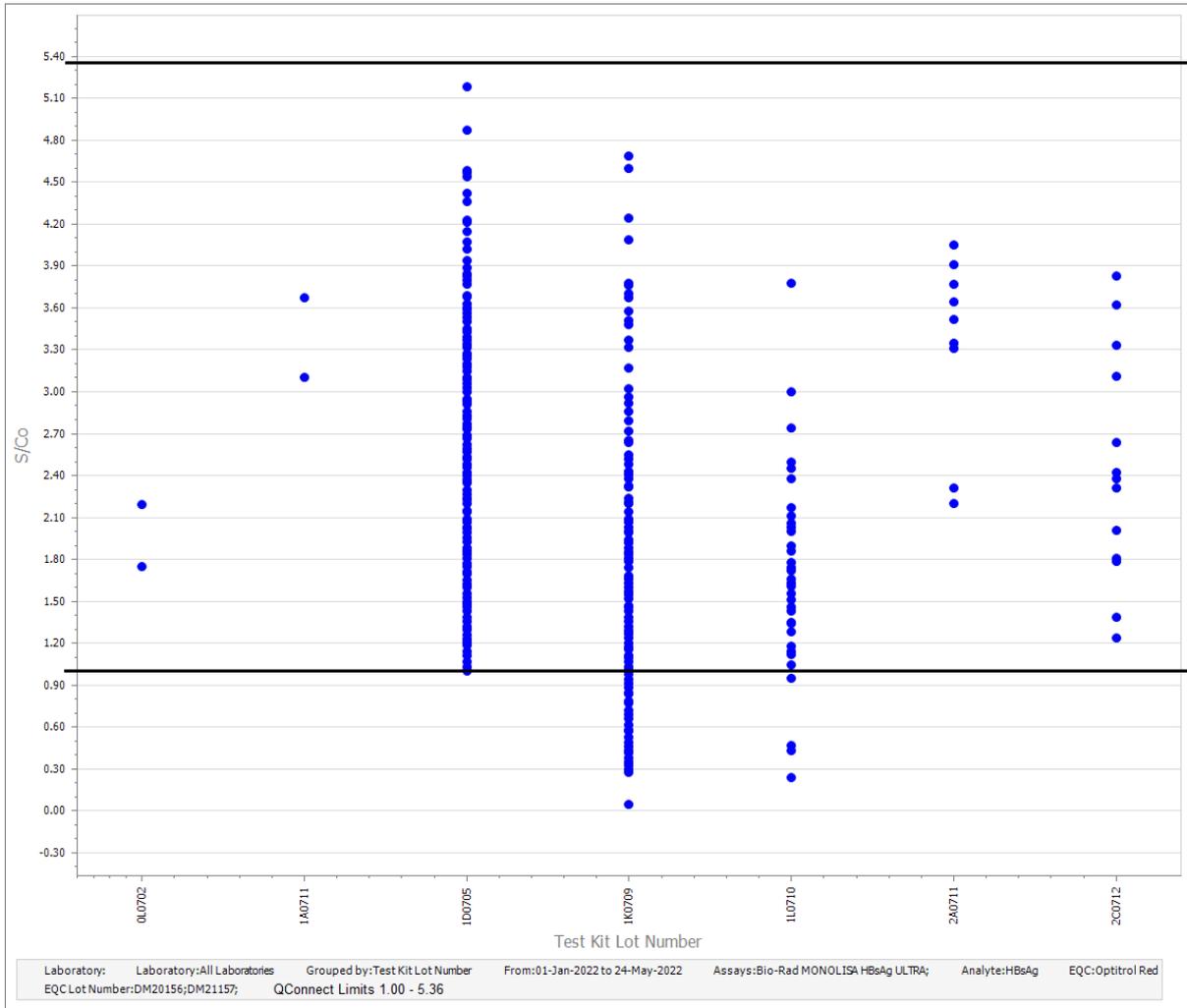


Figure 2 – Peer group data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.

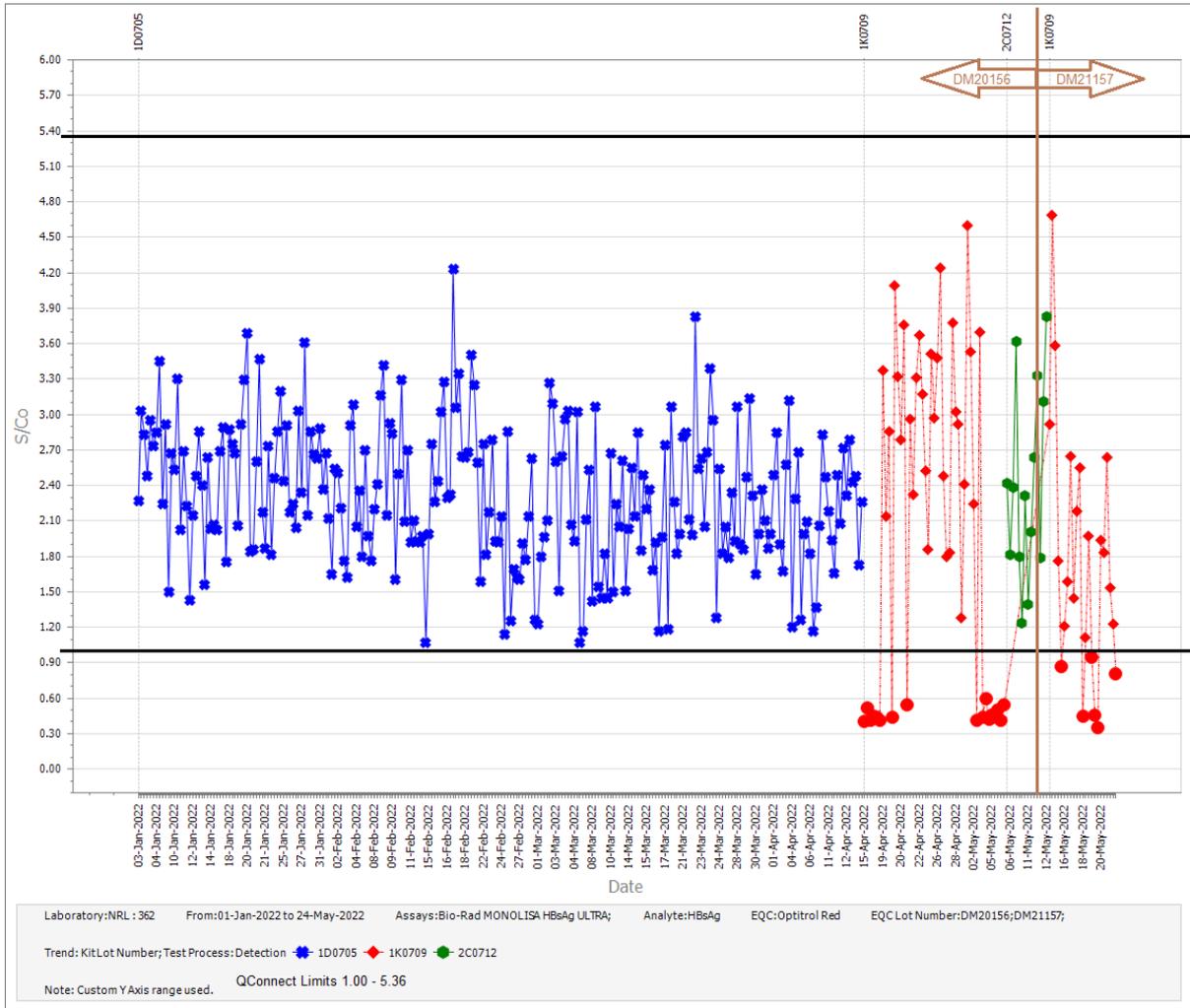


Figure 3 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.

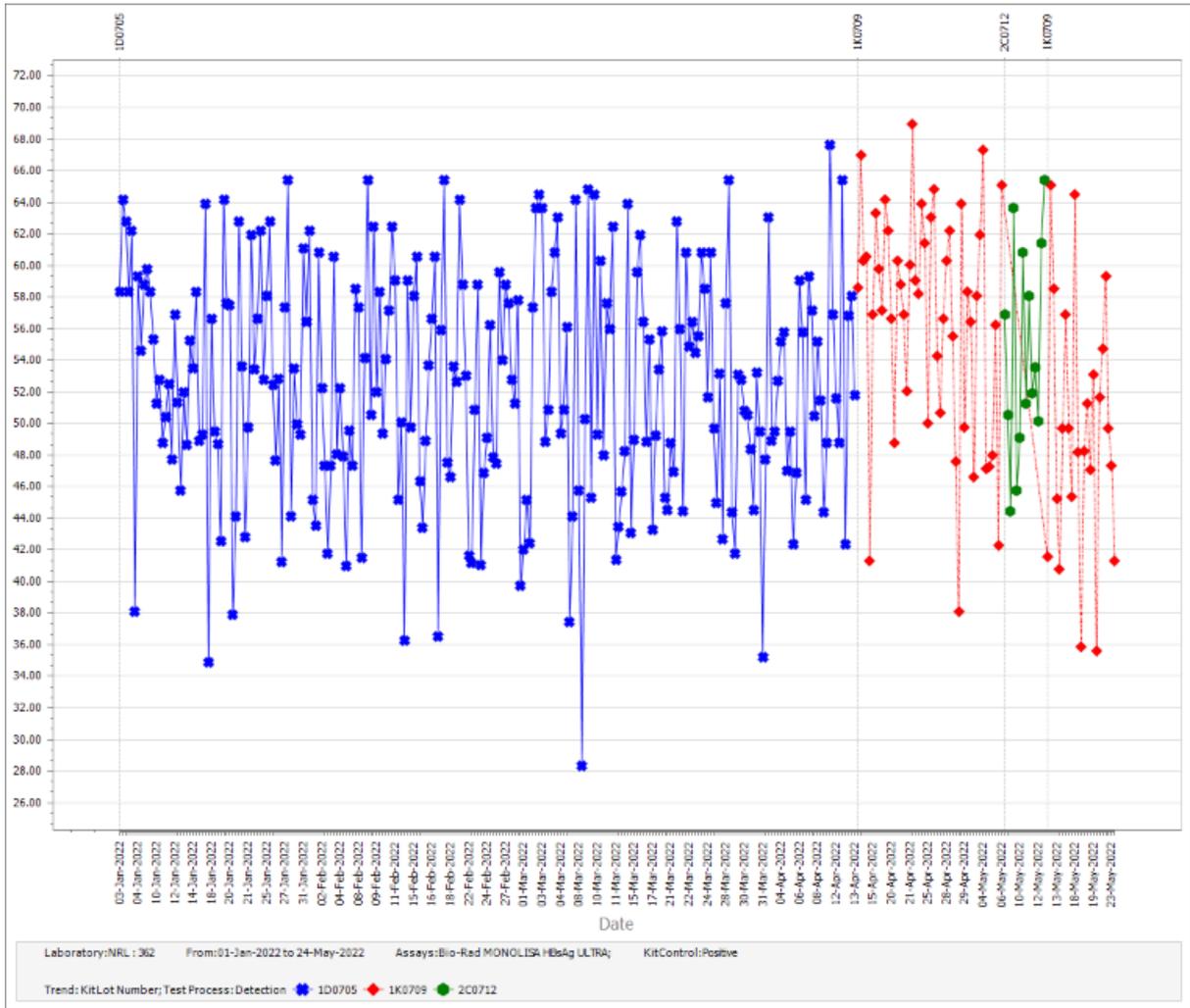


Figure 4 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.

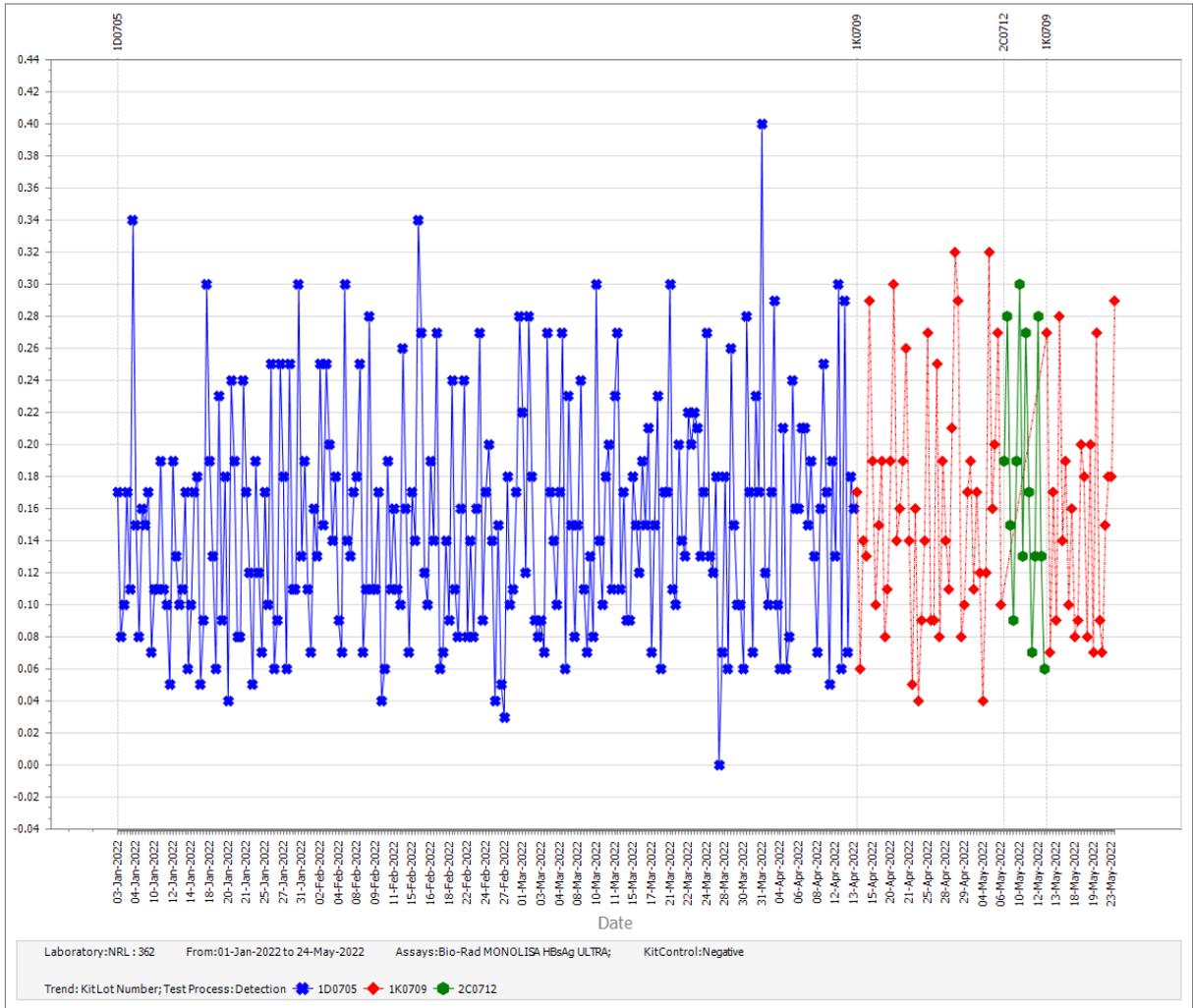


Figure 5 – Participant 362 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.

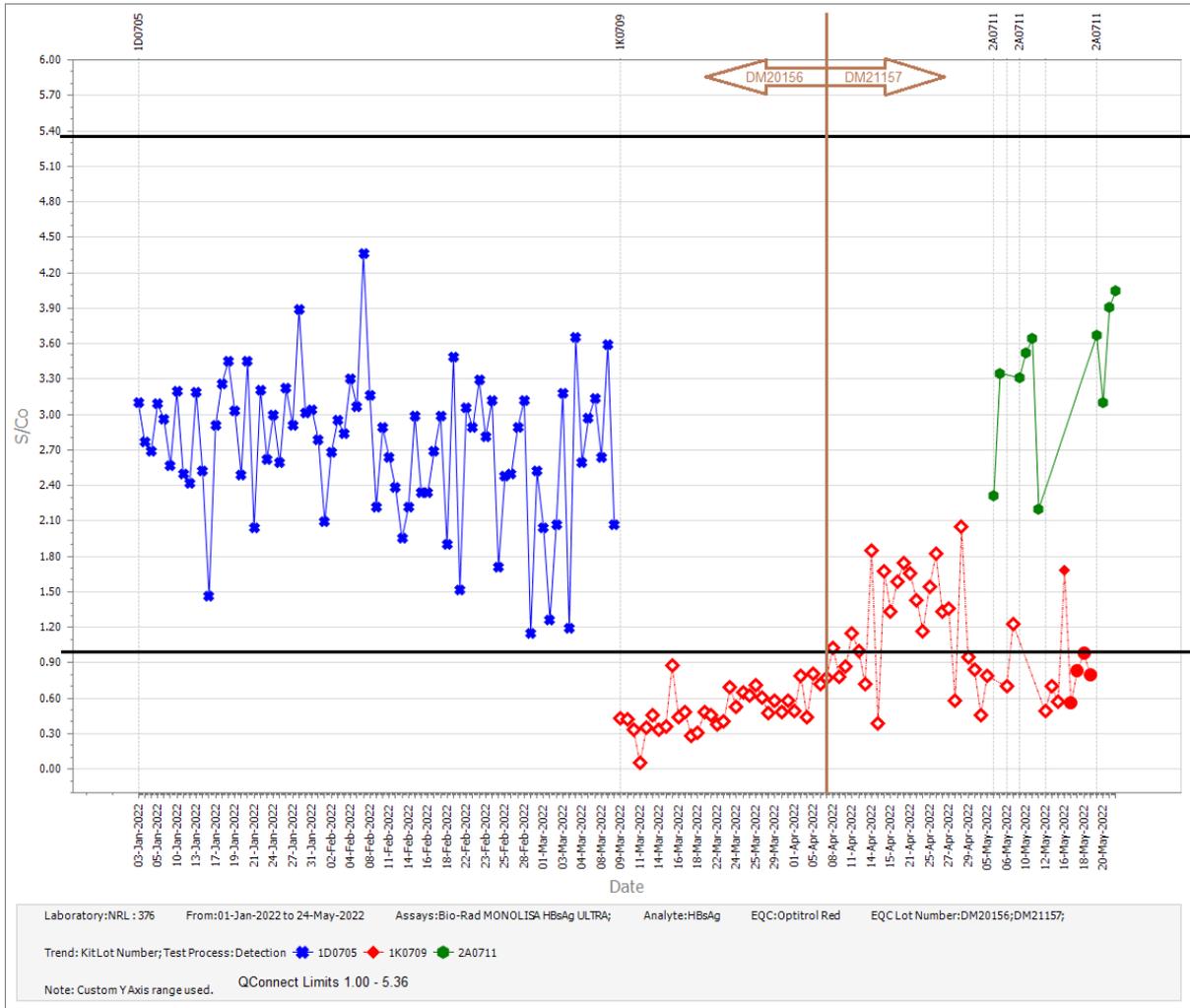


Figure 6 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Optitrol Blue DM20156 and DM21157 by reagent lot.

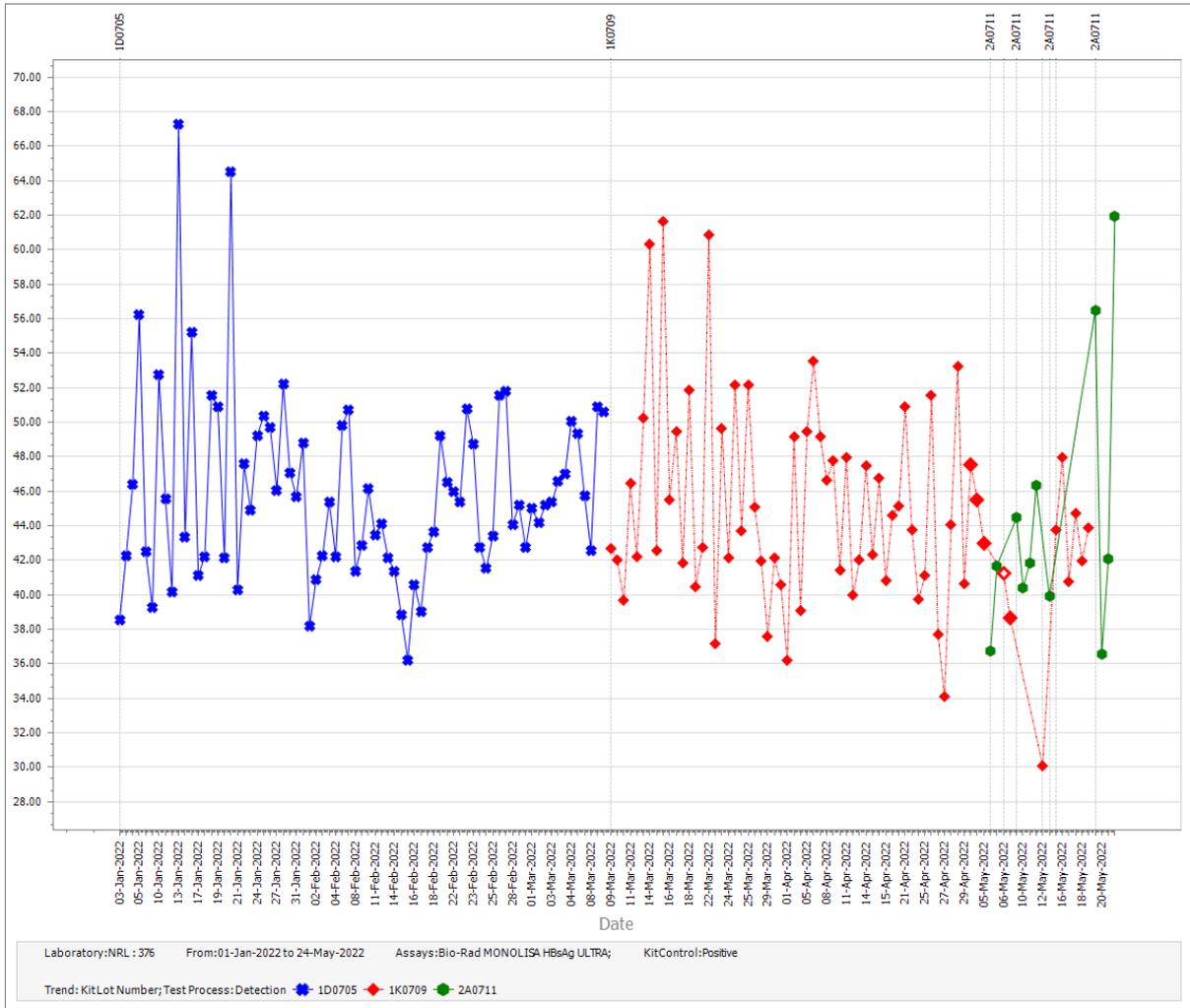


Figure 7 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.

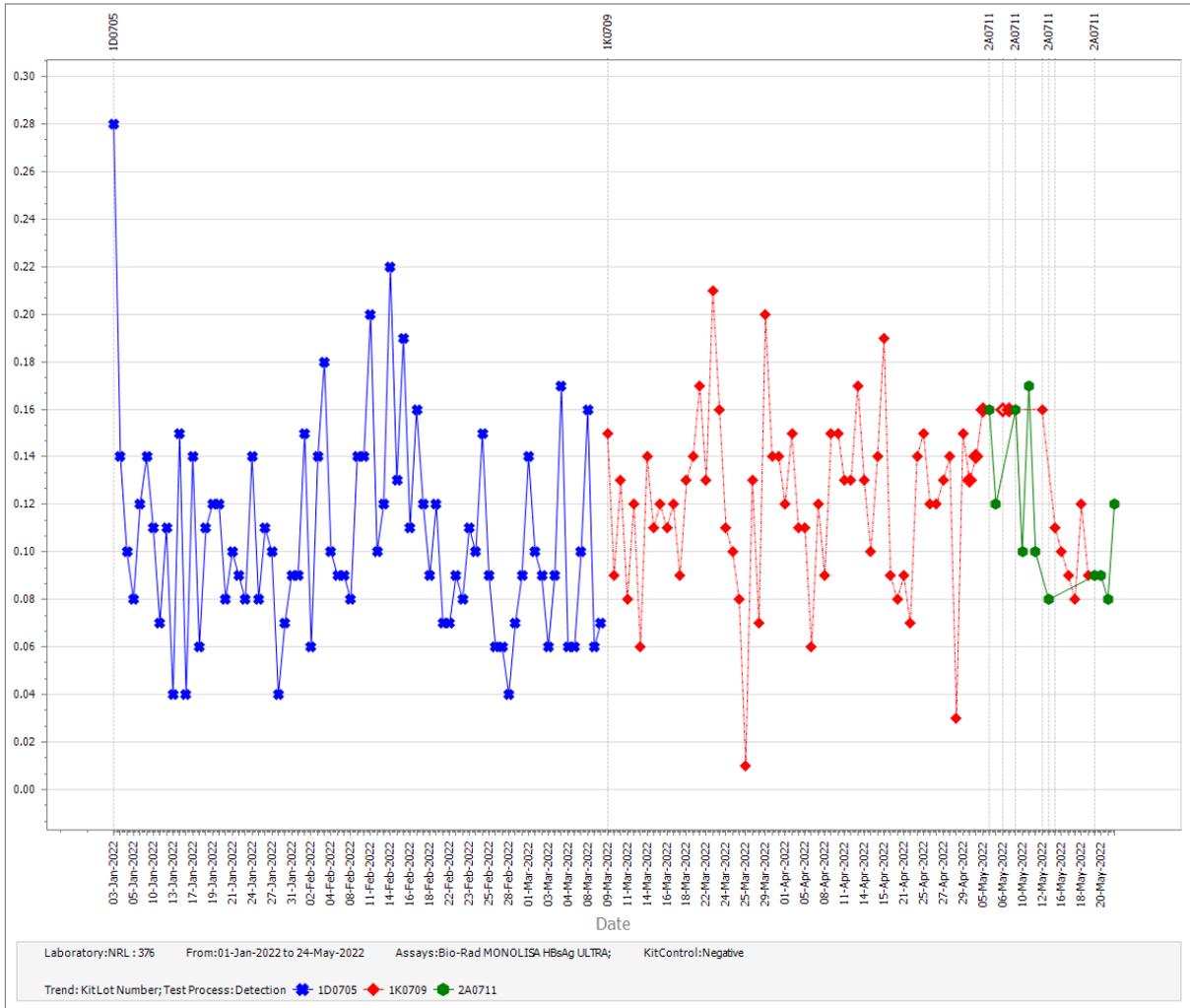


Figure 8 – Participant 376 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.

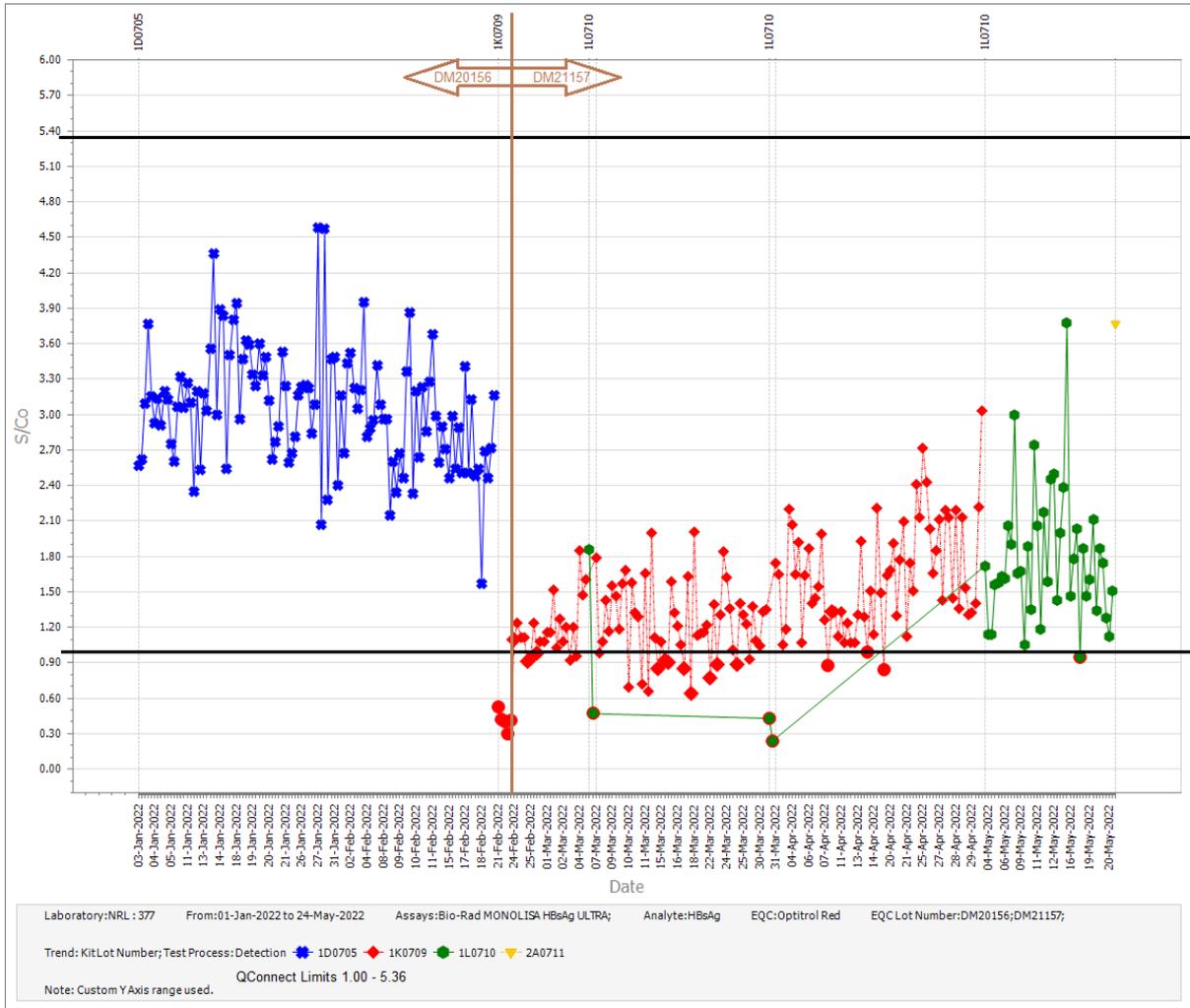


Figure 9 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM20156 and DM21157 by reagent lot.

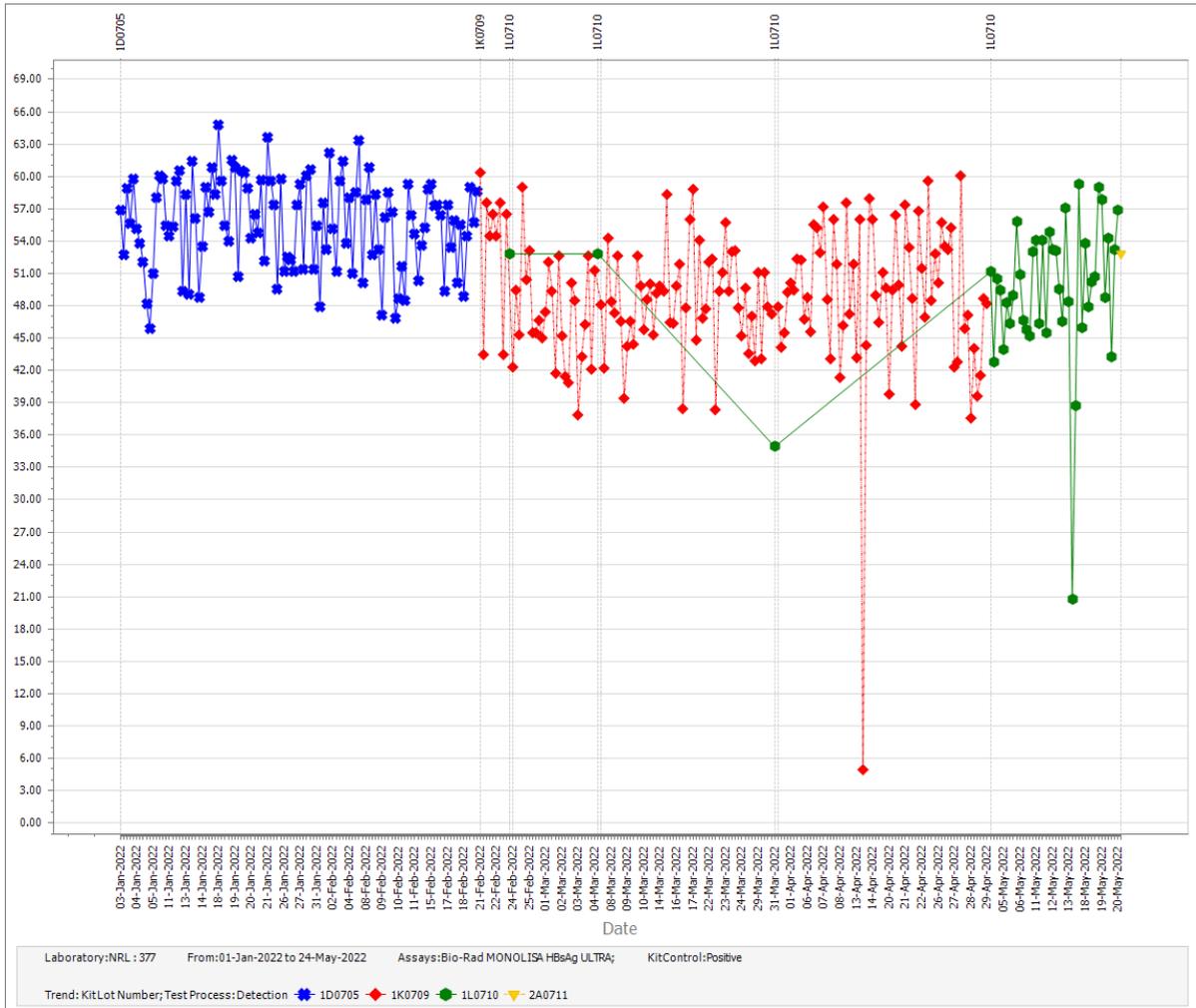


Figure 10 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.

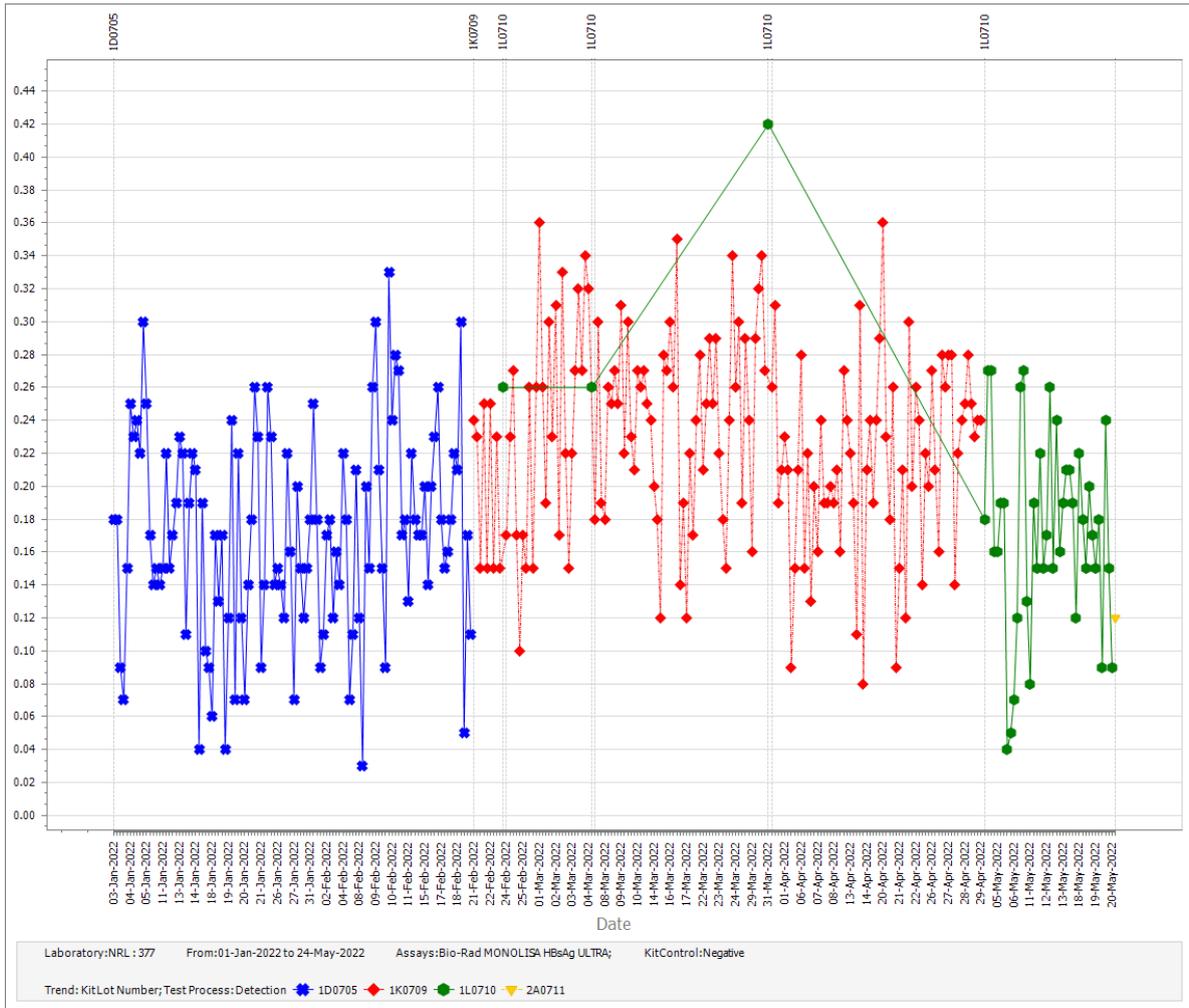


Figure 11 – Participant 377 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.

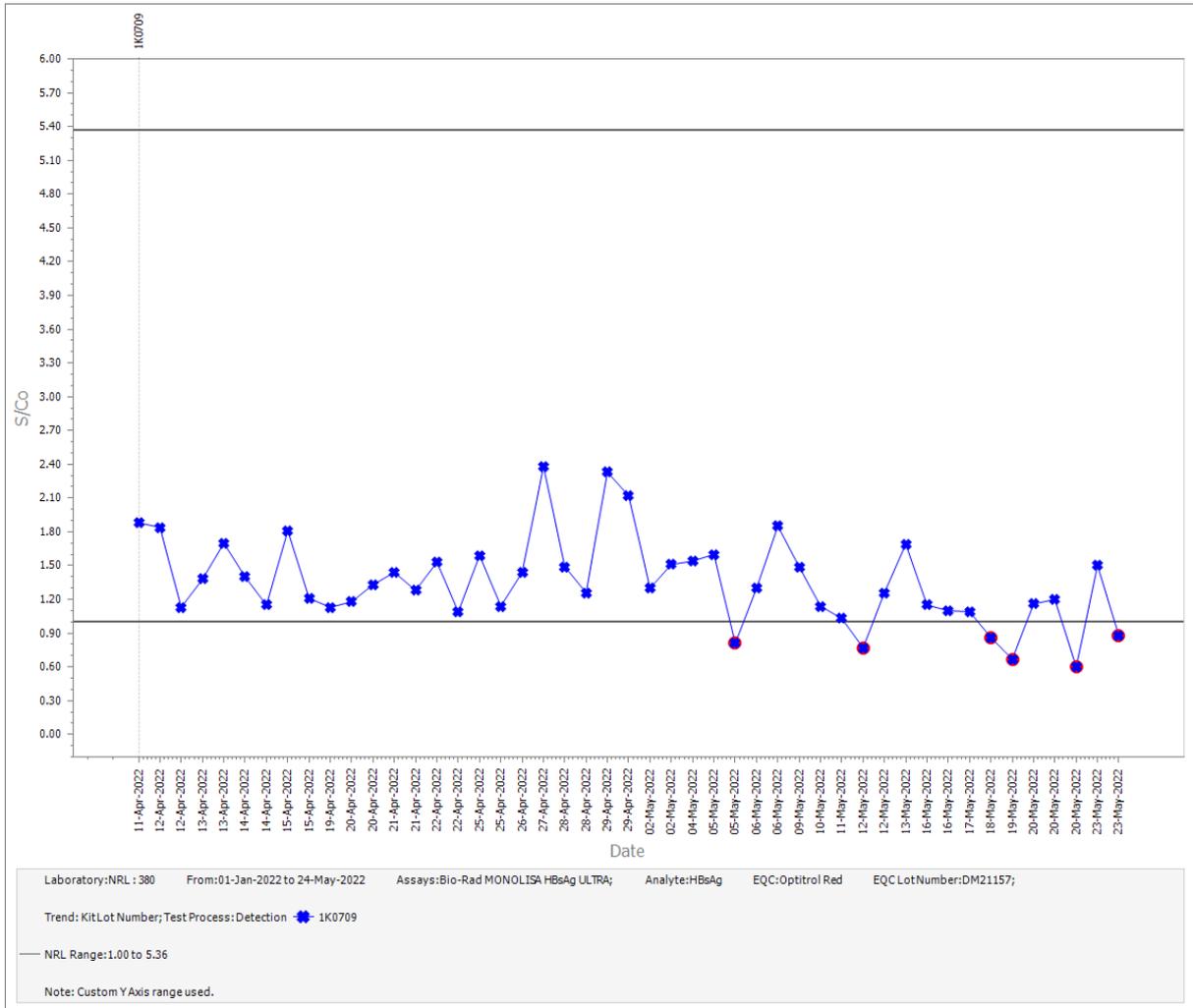


Figure 12 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay, Optitrol Blue DM21157 by reagent lot.

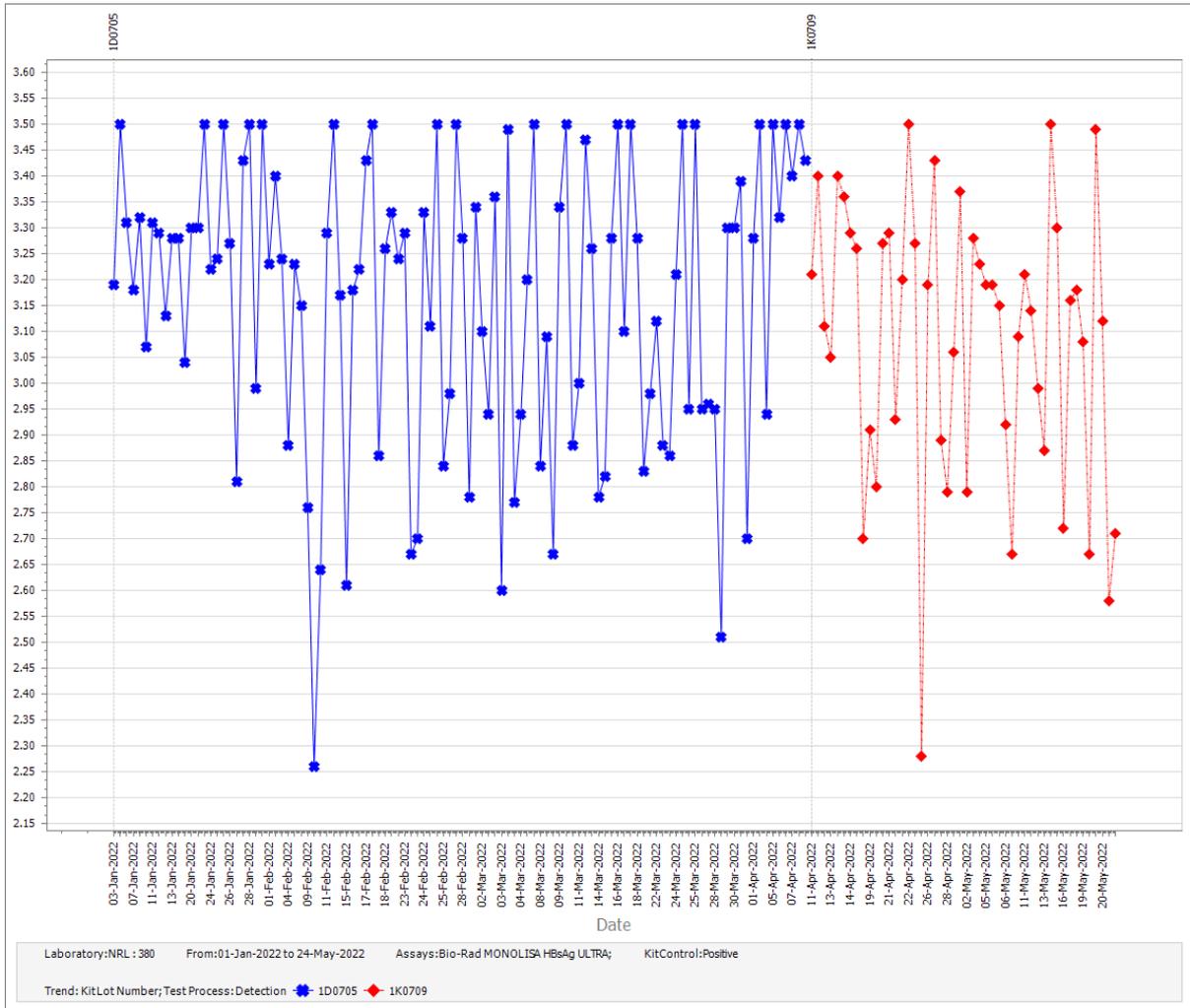


Figure 13 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Positive Kit Control by reagent lot.

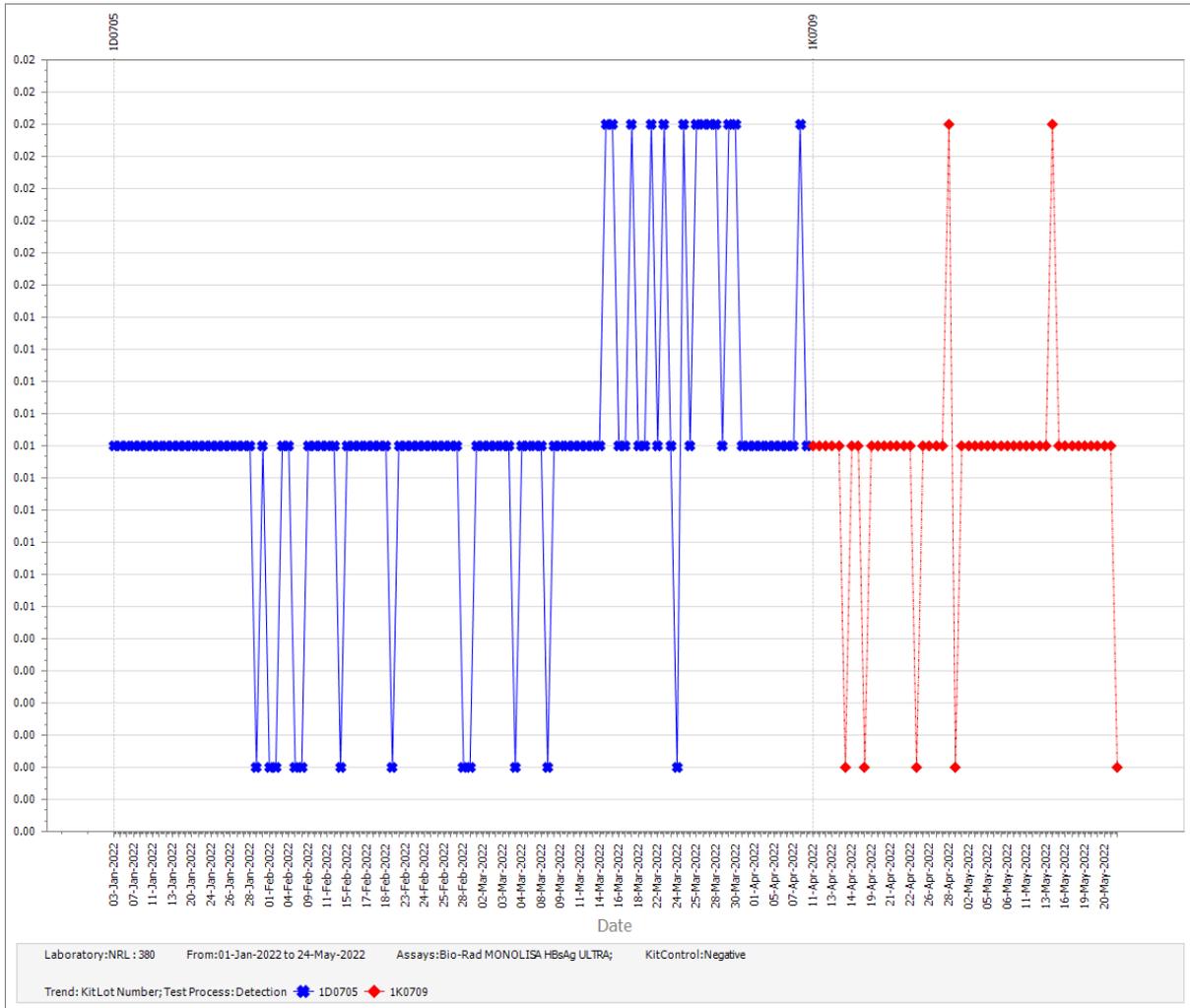


Figure 14 – Participant 380 data for Bio-Rad MONOLISA HBsAg ULTRA assay – Negative Kit Control by reagent lot.