



QC SEROLOGY INVESTIGATION PMM-QC-860

NRL is a:

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- **A World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.**

Report prepared by Kylie Davies

Report authorised by Joe Vincini

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4th Floor Healy Building
41 Victoria Parade
FITZROY VICTORIA 3065
AUSTRALIA

T: +61 3 9418 1111
F: +61 3 9418 1155
www.nrlquality.org.au
A.B.N. 52 004 705 640



1 INTRODUCTION

NRL was contacted by Participant 8, to investigate a downward trend observed for QConnect HEPR lot DM20291 when testing with the Abbott Alinity i Anti-HBs and Anti-HAV IgG assays.

2 FINDINGS

- Figure 1 – Participant 8 data for Abbott Alinity i Anti-HBs; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 2 – Participant 8 data for Abbott Alinity i HAV Ab – IgG; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 3 – Participant 8 data for Abbott Alinity i Anti-HBe; QConnect HEPR lot DM20291 by reagent lot, illustrating no trend down in data.
- Figure 4- Participant 8 data for Abbott Alinity i Anti-HBs; QConnect HEPR lot DM20026 by reagent lot, illustrating trend down in data.
- Figure 5 – Participant 8 data for Abbott Alinity i Anti-HAV Ab IgG, QConnect HEPR; DM20026 by reagent lot.
- Figure 6- Participant 8 data for Abbott Alinity i Anti-HBs; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot, illustrating trend down in data observed on only DM20026 and DM20219.
- Figure 7 - Participant 8 data for Abbott Alinity i Anti-HAV Ab IgG; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot, illustrating trend down in data observed on only DM20026 and DM20219.
- Figure 8 - Participant 8 data for Abbott Alinity i Anti-HBe; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot, illustrating shift up in data for DM20026 and DM20219.
- Figure 9 - Peer group data for Alinity i Anti-HBs, QConnect HEPR DM20291 by participant, illustrating consistent data across peer group.
- Figure 10 - Peer group data for Alinity i Anti-HAV Ab IgG, QConnect HEPR DM20291 by participant, illustrating consistent data across peer group.
- Figure 11 - Peer group data for Alinity i Anti-HBe, QConnect HEPR DM20291 by participant, illustrating consistent data across peer group.

- Figure 12 - Participant 1015 data for Abbott Alinity i Anti-HBs; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 13 – Participant 1015 data for Abbott Alinity i Anti-HAV Ab IgG; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 14 – Participant 50 data for Abbott Alinity i Anti-HBs; QConnect HEPR lots DM20026 and DM20291 by reagent lot, illustrating trend down in data.
- Figure 15 – Peer group data for Abbott ARCHITECT Anti-HBs, QConnect HEPR DM20291, illustrating consistency in data across the peer group.
- Figure 16 – Participant 40 data for Abbott ARCHITECT Anti-HBs; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 17- Participant 129 data for Abbott ARCHITECT Anti-HBs; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 18 – Peer group data for Abbott ARCHITECT Anti-HAV Ab IgG, QConnect HEPR DM20291, illustrating consistency in data across the peer group.
- Figure 19 – Participant 40 data for Abbott ARCHITECT Anti-HAVb IgG; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 20 – Participant 129 data for Abbott ARCHITECT Anti-HAVb IgG; QConnect HEPR lot DM20291 by reagent lot, illustrating trend down in data.
- Figure 21 – Peer group data for Roche Elecsys Anti-HBs II, QConnect HEPR DM20291, illustrating consistency in data across the peer group.
- Figure 22 - Participant 46 data for Roche Elecsys Anti-HBs II; QConnect HEPR lot DM20291 by reagent lot, illustrating trend in data.
- Figure 23 – Participant 147 data for Roche Elecsys Anti-HBs II; QConnect HEPR lot DM20291 by reagent lot, illustrating variation in data.
- Figure 24 - Peer group data for DiaSorin LIAISON XL Murex anti-HBs, QConnect HEPR DM20291.
- Figure 25 - Participant 13 data for DiaSorin LIAISON XL Murex anti-HBs, QConnect HEPR DM20291, illustrating trend down in data.

3 DISCUSSION

When investigating the downward trend reported by Participant 8 for QConnect HEPR lot DM20291 testing with the Abbott Alinity i Anti-HBs and Anti-HAV IgG assays, data from all participants in the peer group were investigated to establish whether there was any evidence of trends or patterns across the peer group. Data from all platforms where QConnect HEPR was utilised were also reviewed to establish if the trend was evident across more than one peer group.

Figures 1, 2 and 3 show data reported by Participant 8 for QConnect HEPR lot DM20291 testing with the Abbott Alinity i Anti-HBs and Anti-HAV IgG assays. The only assay to show no downward trend was the Abbott Alinity i Anti-HBe assay, a competitive assay (Figure 3).

Figures 4 and 5 show data reported by Participant 8 for QConnect HEPR lot DM20026 on the Abbott Alinity i Anti-HBs and Anti-HAV IgG assays. Both assays show the same downward trend observed on QConnect HEPR lot DM20291.

Figures 6, 7 and 8 show data reported by Participant 8 for all QConnect HEPR lots in use, DM19008, DM20026 and DM20291 on the Abbott Alinity i Anti-HBs, Anti-HAV IgG and Anti-HBe assays testing with Figures 4 and 5 illustrate the downward trend occurring on the previous QConnect HEPR lot DM20026. QConnect HEPR lot DM19008 showed no evidence of a downward trend on any of the three assays in use.

Figures 9,10 and 11 show peer group data for QConnect HEPR; DM20291 testing on Abbott Alinity i Anti-HBs, Anti-HAV IgG and Anti-HBe assays, respectively. All three assays show consistent data entry across the peer group indicating the likelihood the downward trend identified for participant 8 is occurring for other participants.

Figures 12 and 13 show data reported by Participant 1015 for QConnect HEPR; DM20291 testing on the Abbott Alinity i Anti-HBs and Anti-HAV IgG assays, respectively. The same downward trend observed for Participant 8 is observed on both assays for Participant 1015. Figure 14 show data reported by Participant 50 for QConnect HEPR lots DM20026 and DM20291 testing on the Abbott Alinity i Anti-HBs. The same downward trend observed for participant 8 is observed on both HEPR lots, however less severe for DM20291, for participant 50. Participant 50 had submitted no data for the Abbott Alinity i Anti-HAV IgG assay so no comparison could be made.

Figures 15 and 18 show peer group data for QConnect HEPR DM20291 for the Abbott ARCHITECT Anti-HBs and Anti-HBe assays respectively, illustrating consistent data entry across the peer group for both assays.

Participants 1015 and 40 were selected for further investigation as they had reported data for both the Abbott ARCHITECT Anti-HBs and Anti-HBe assays testing with HEPR; DM20291. Both participants showed the same downward trend identified for Participant 8 on the Alinity i platform, for both ARCHITECT assays (Figures 16, 17, 19 and 20).

As QConnect HEPR is utilised across multiple assay manufacturers and platforms these peer groups were also investigated.

Figures 21, 22 and 23 show data for QConnect HEPR DM20291 on the Roche Elecsys Anti-HBs II assay, by peer group, Participant 46 and Participant 147 respectively. As observed on both the Abbott platforms the peer group data is constant and individual participant data shows the same previously identified downward trend.

Figures 24 and 25 show data for QConnect HEPR DM20291 on the DiaSorin LIAISON XL Murex anti-HBs assay. Only one participant, Participant 13, had data entered for this assay / QC lot combination. Figure 25 illustrates the same downward trend observed for all previously mentioned platforms.

Reviewing data for all platforms that utilised QConnect HEPR; DM20291, Abbott ARCHITECT and Alinity i, Roche Elecsys and DiaSorin LIASION XL, it was observed that the downward trend was present across all peer groups and the likely cause of this trend is a QC manufacturing or production lot issue. The downward trend was also observed for the previous QConnect HEPR lot, DM20026.

4 RECOMMENDATIONS

NRL recommends that DiaMex review the production and manufacturing of both QConnect HEPR lots, DM20026 and DM20291.

NRL requests a new production lot from DiaMex for Australian participants.

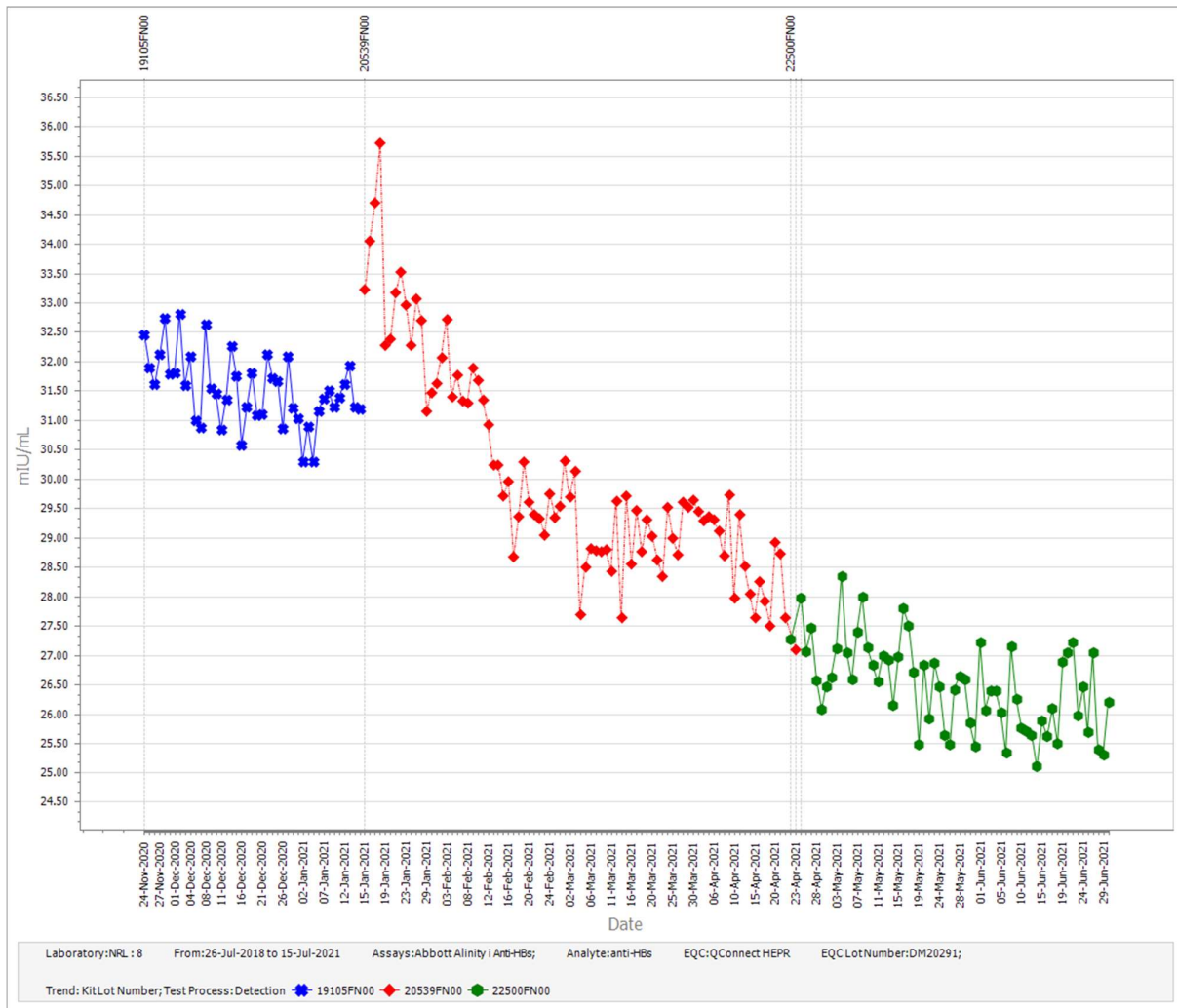


Figure 1 – Participant 8 data for Abbott Alinity i Anti-HBs, QConnect HEPR; DM20291 by reagent lot.

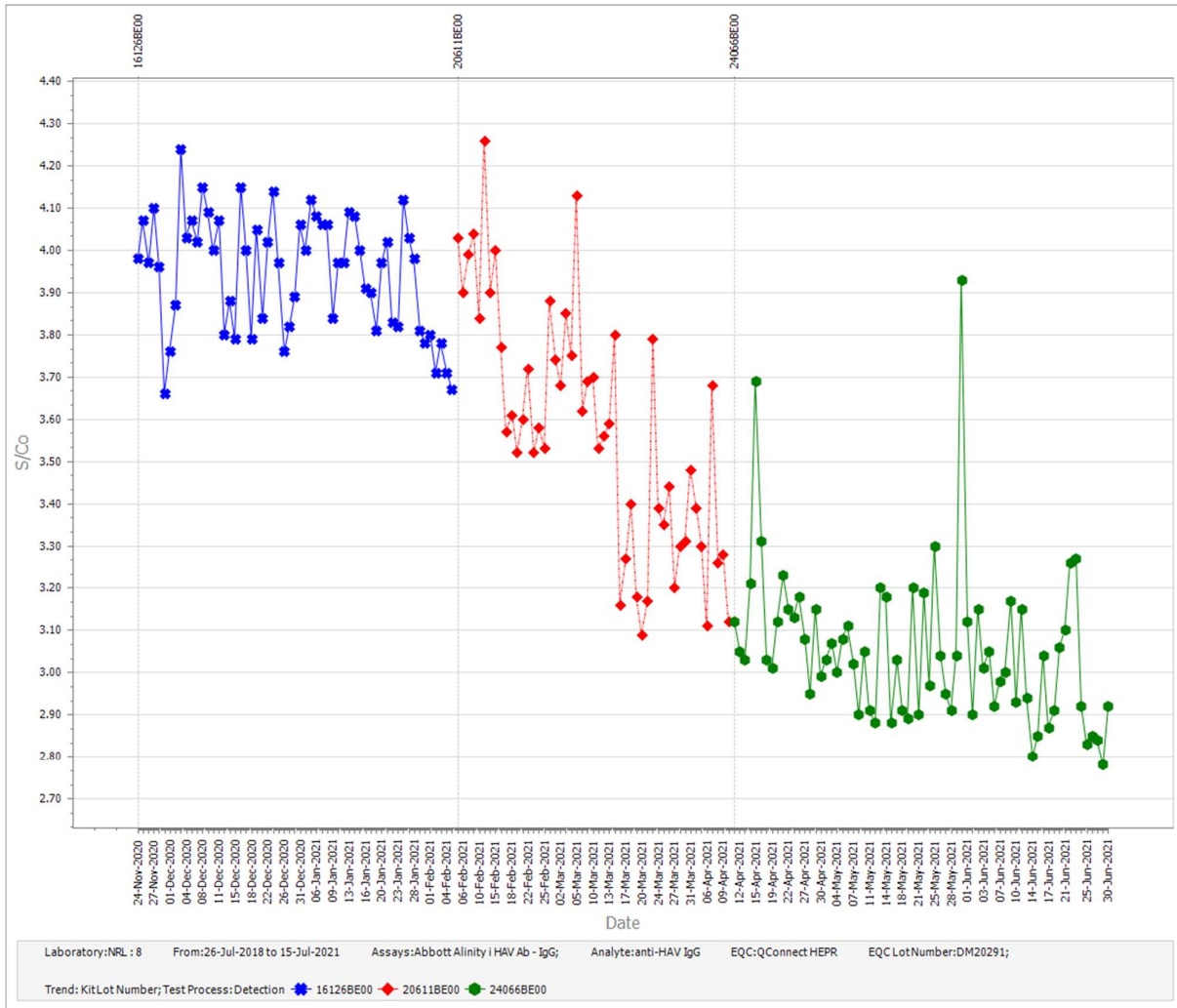


Figure 2 – Participant 8 data for Abbott Alinity i HAV Ab – IgG; DM20291 by reagent lot.

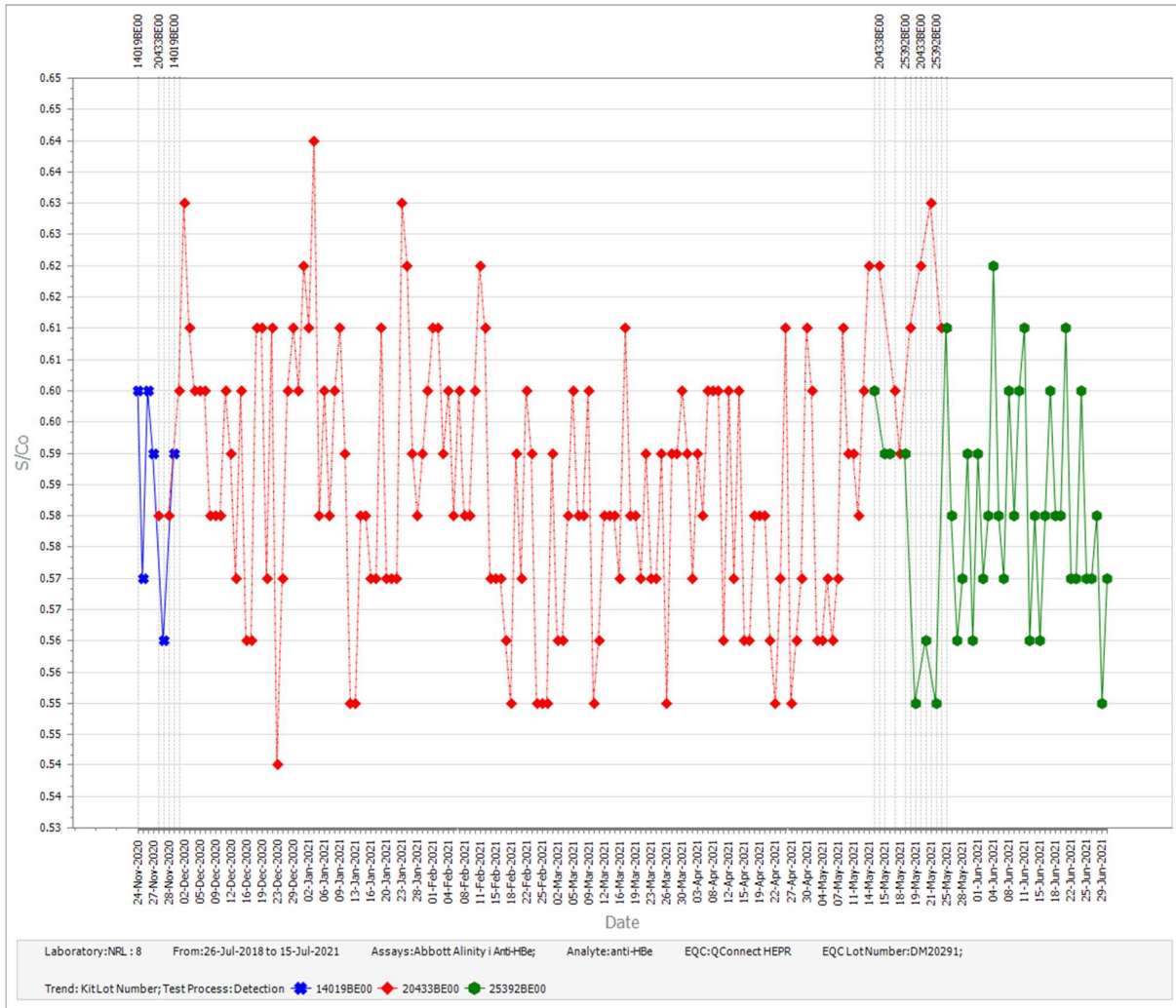


Figure 3 - Participant 8 data for Abbott Alinity i Anti-HBe, QConnect HEPR; DM20291 by reagent lot.

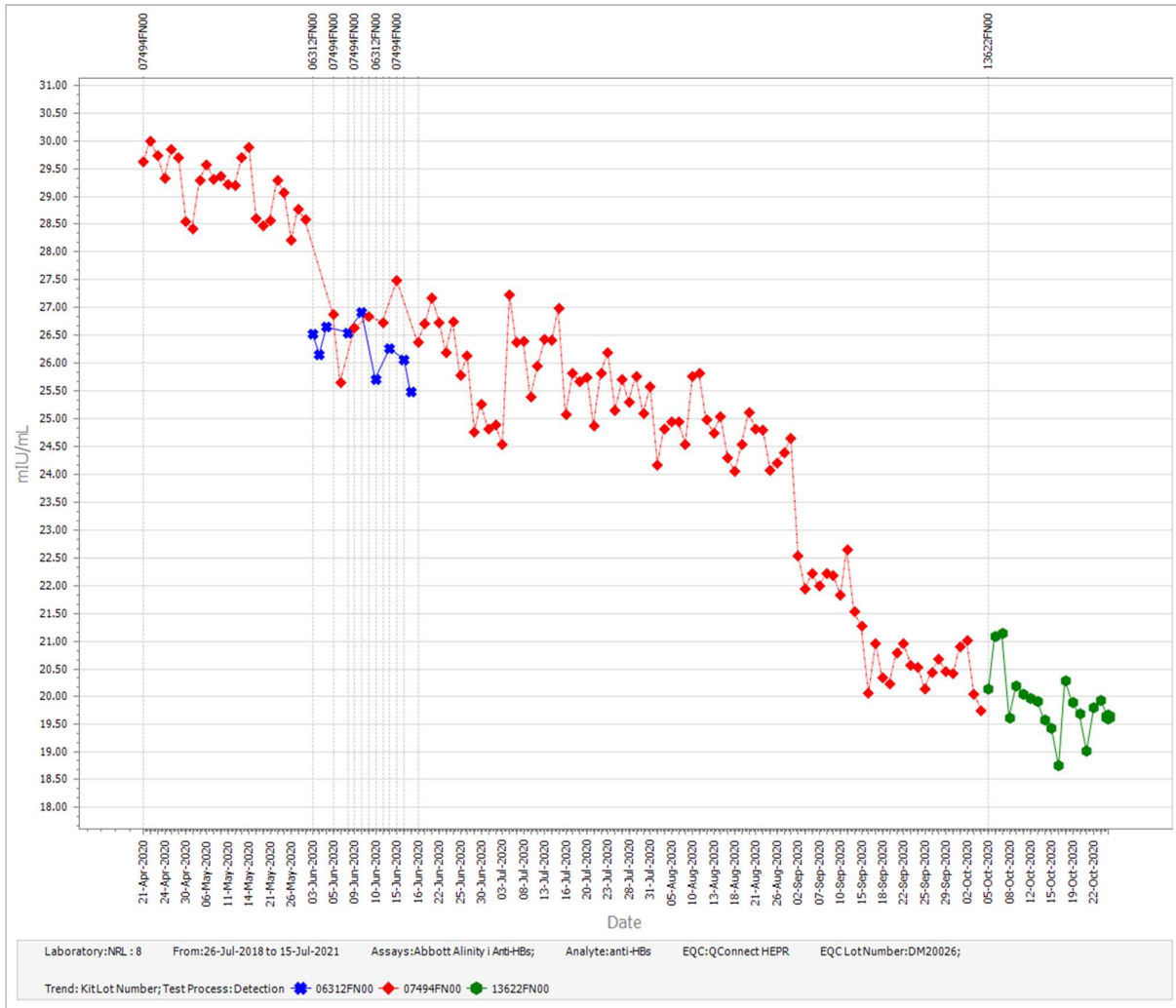


Figure 4 – Participant 8 data for Abbott Alinity i Anti-HBs, QConnect HEPR; DM20026 by reagent lot.

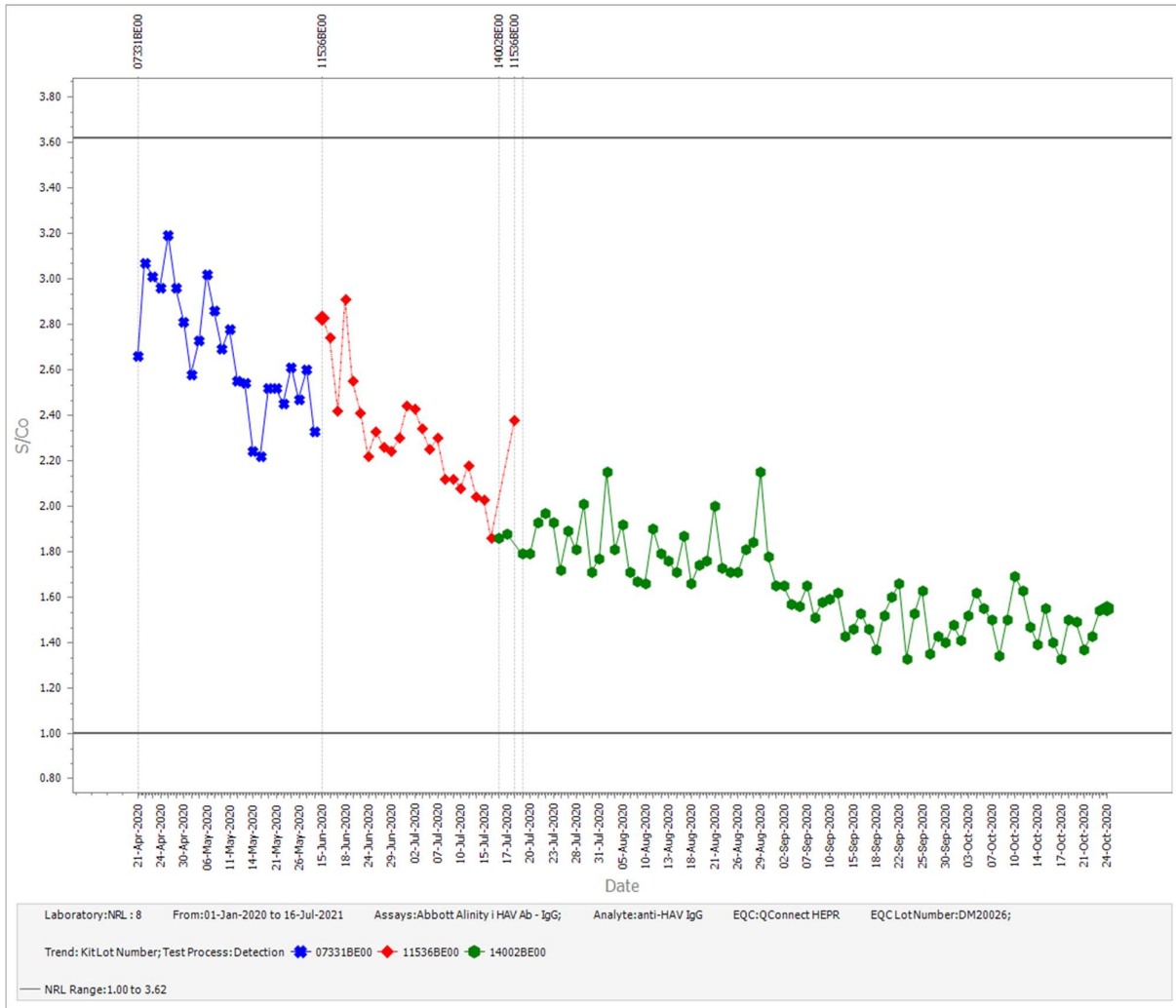


Figure 5 – Participant 8 data for Abbott Alinity i Anti-HAV Ab IgG, QConnect HEPR; DM20026 by reagent lot.

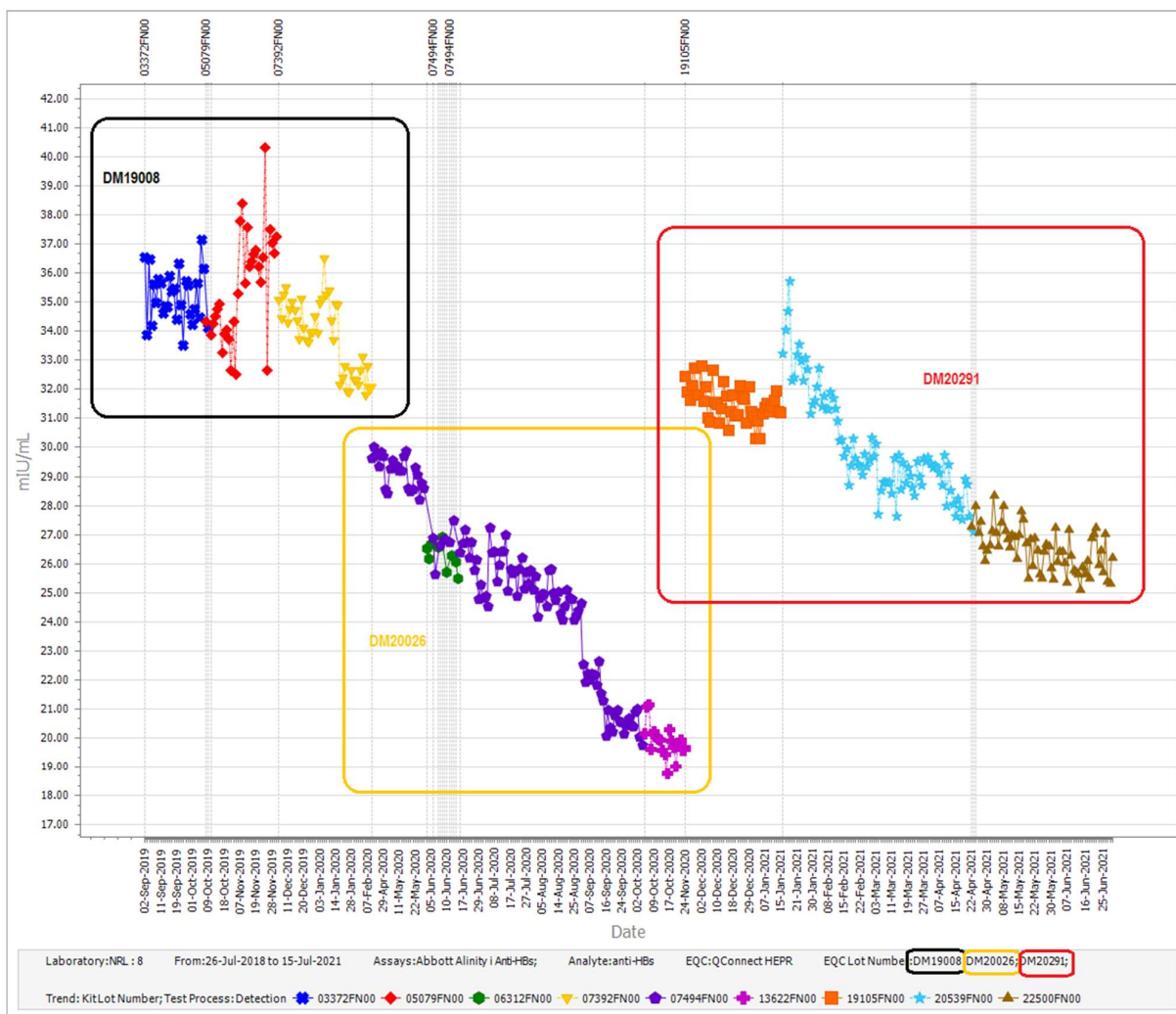


Figure 6 – Participant 8 data for Abbott Alinity i Anti-HBs; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot.

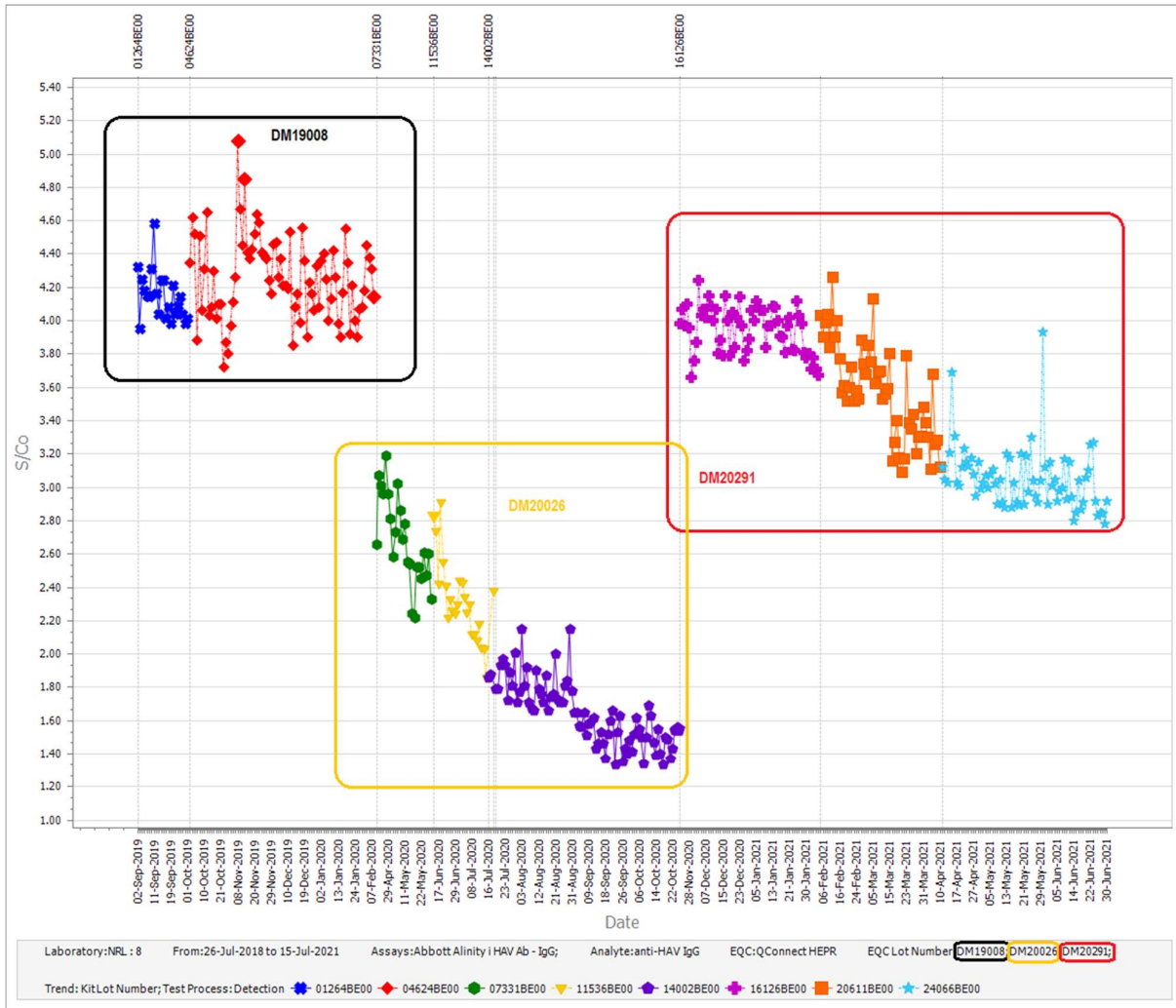


Figure 7 – Participant 8 data for Abbott Alinity i Anti-HAV Ab IgG; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot.

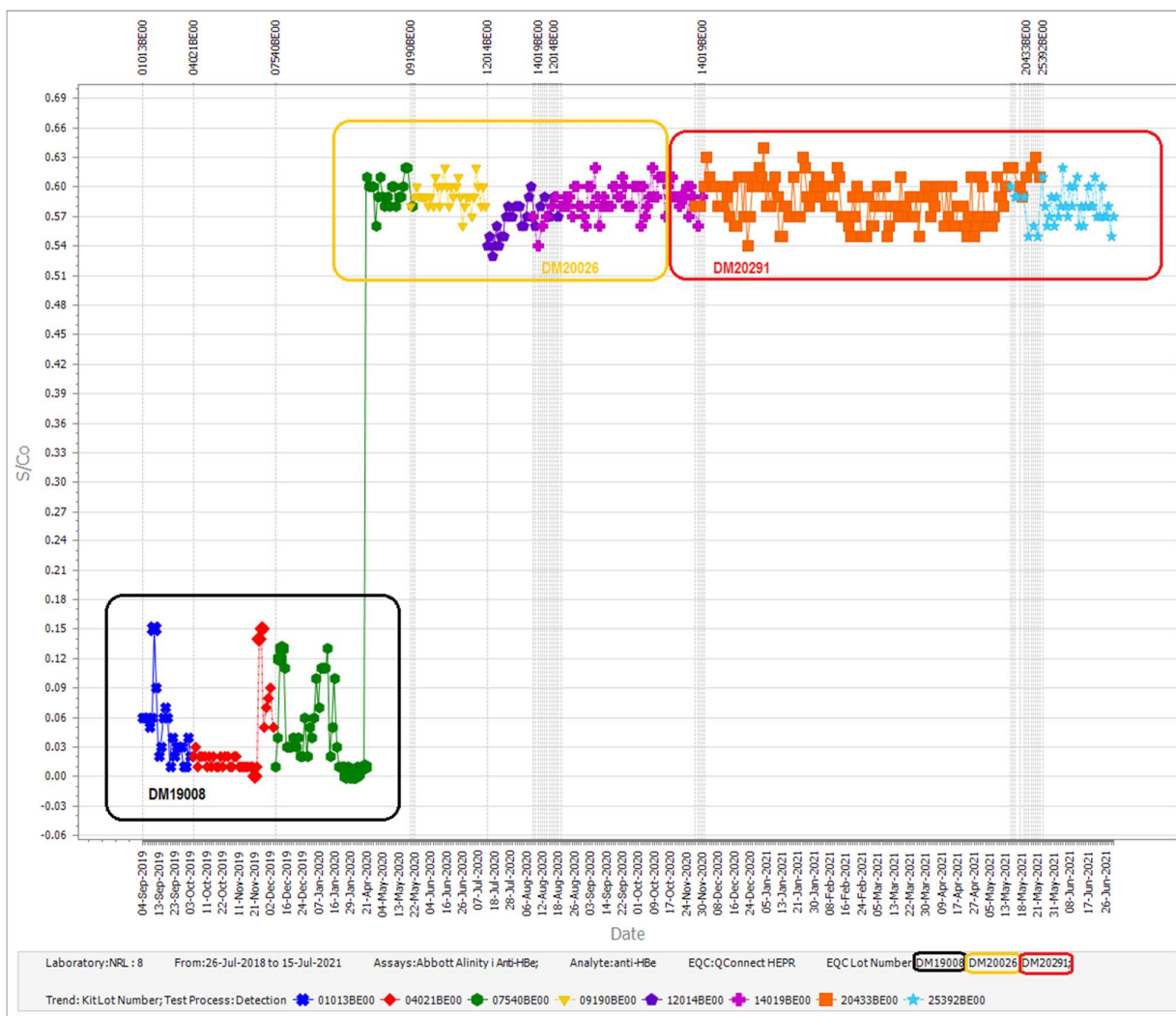


Figure 8 – Participant 8 data for Abbott Alinity i Anti-HBe; QConnect HEPR lots DM19008, DM20026 and DM20291 by reagent lot.

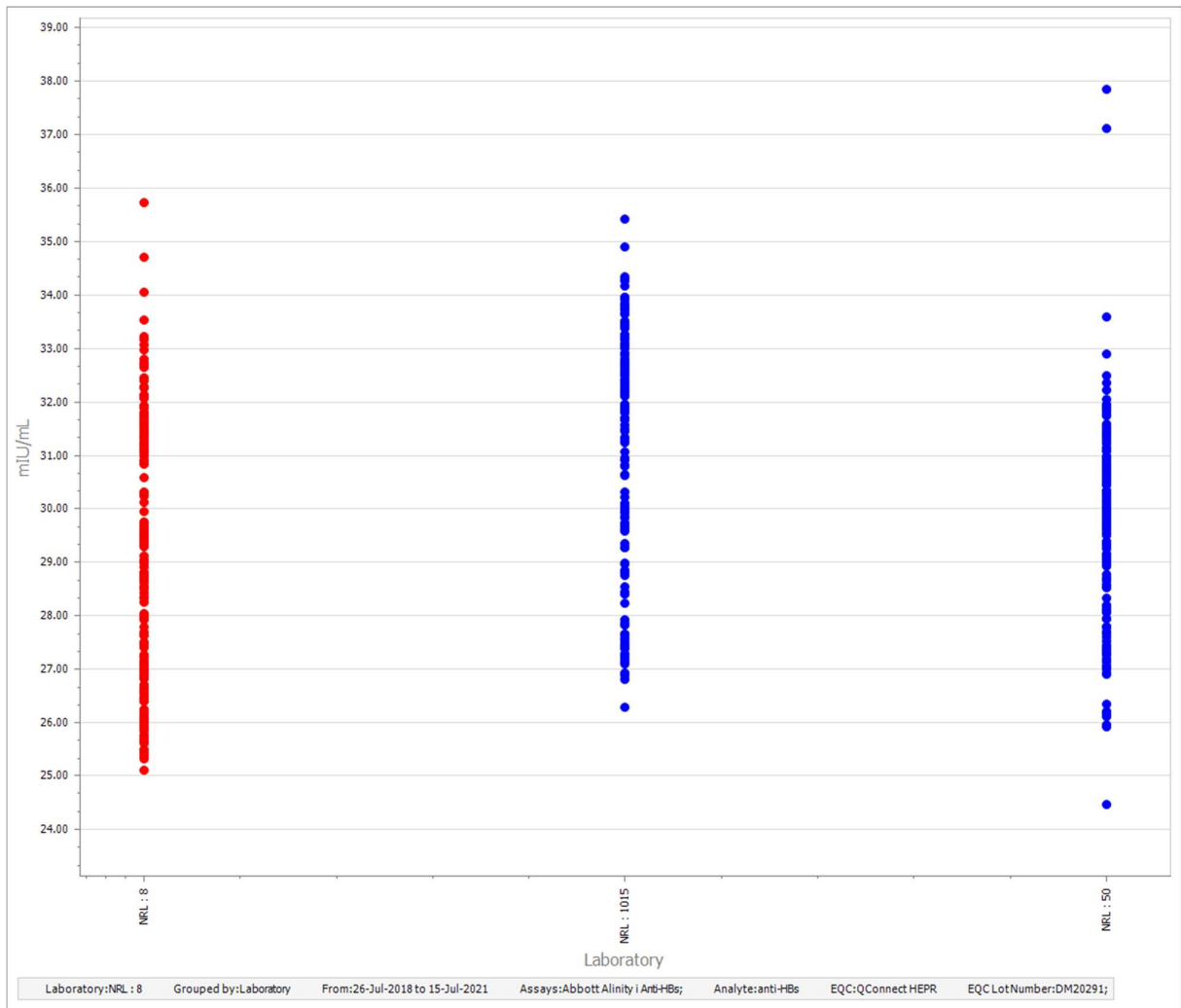


Figure 9 – Peer group data for Alinity i Anti-HBs, QConnect HEPR DM20291 by participant.

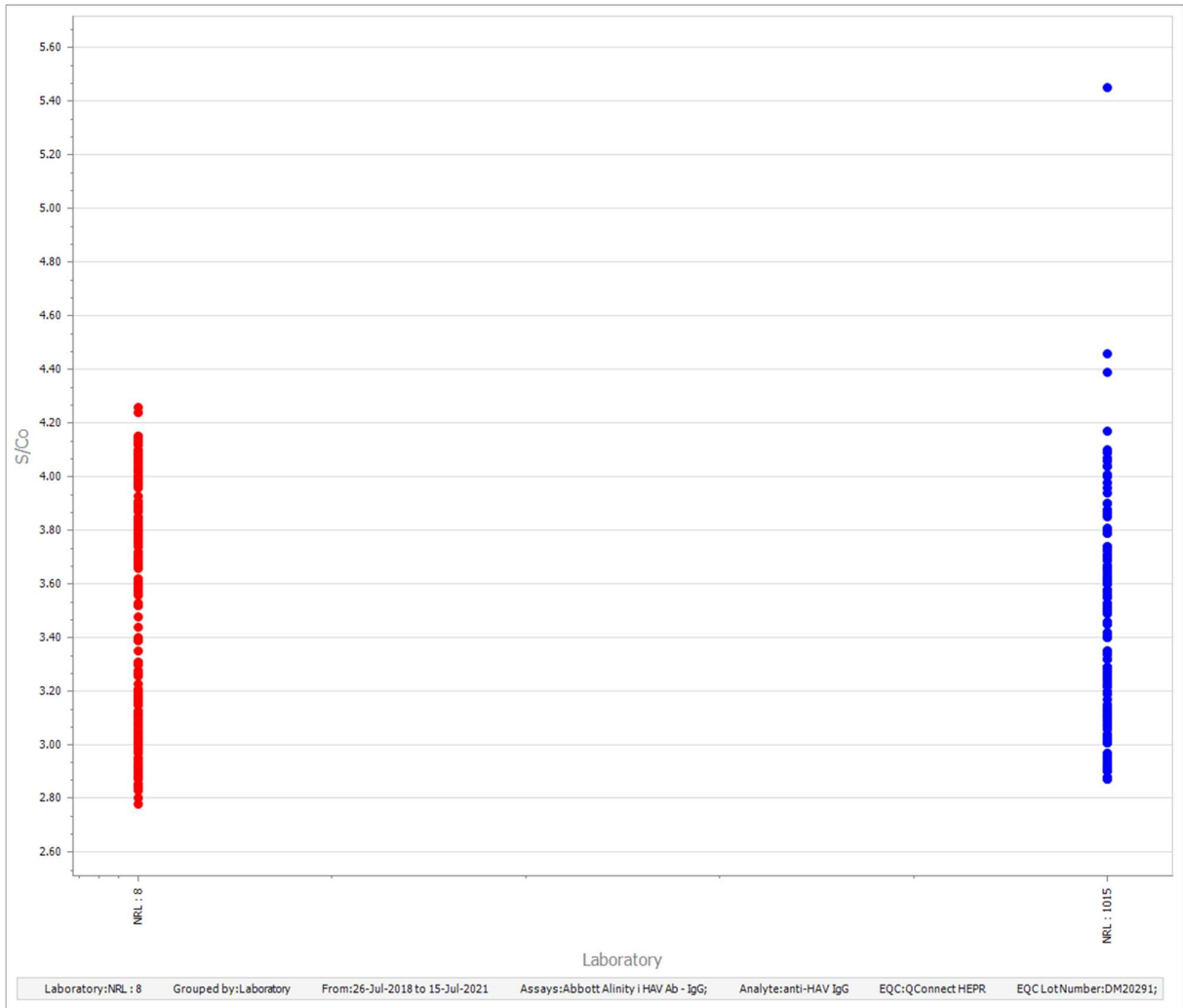


Figure 10- Peer group data for Alinity i Anti-HAV Ab IgG, QConnect HEPR DM20291 by participant.

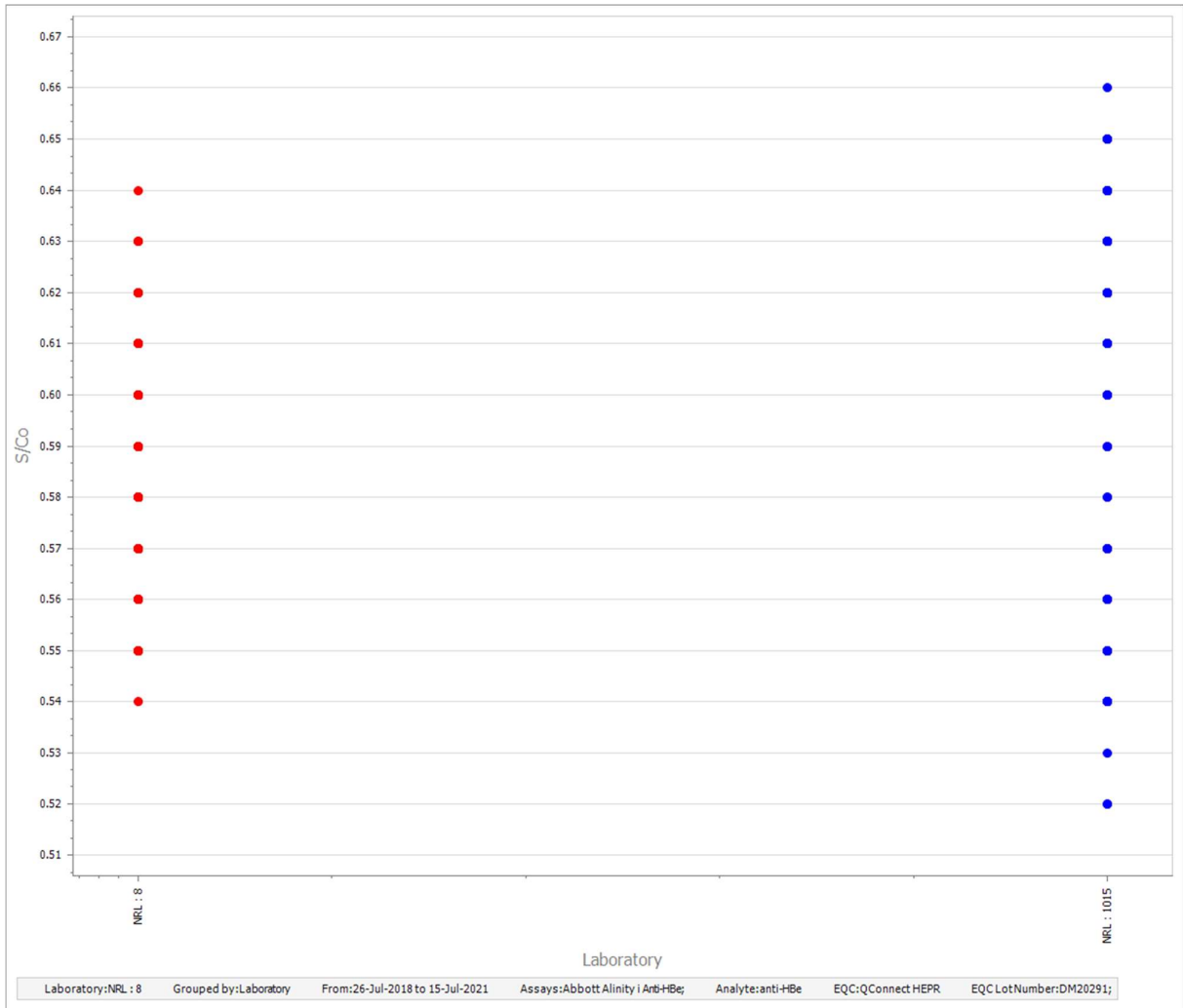


Figure 11 – Peer group data for Alinity i Anti-HBe, QConnect HEPR DM20291 by participant.

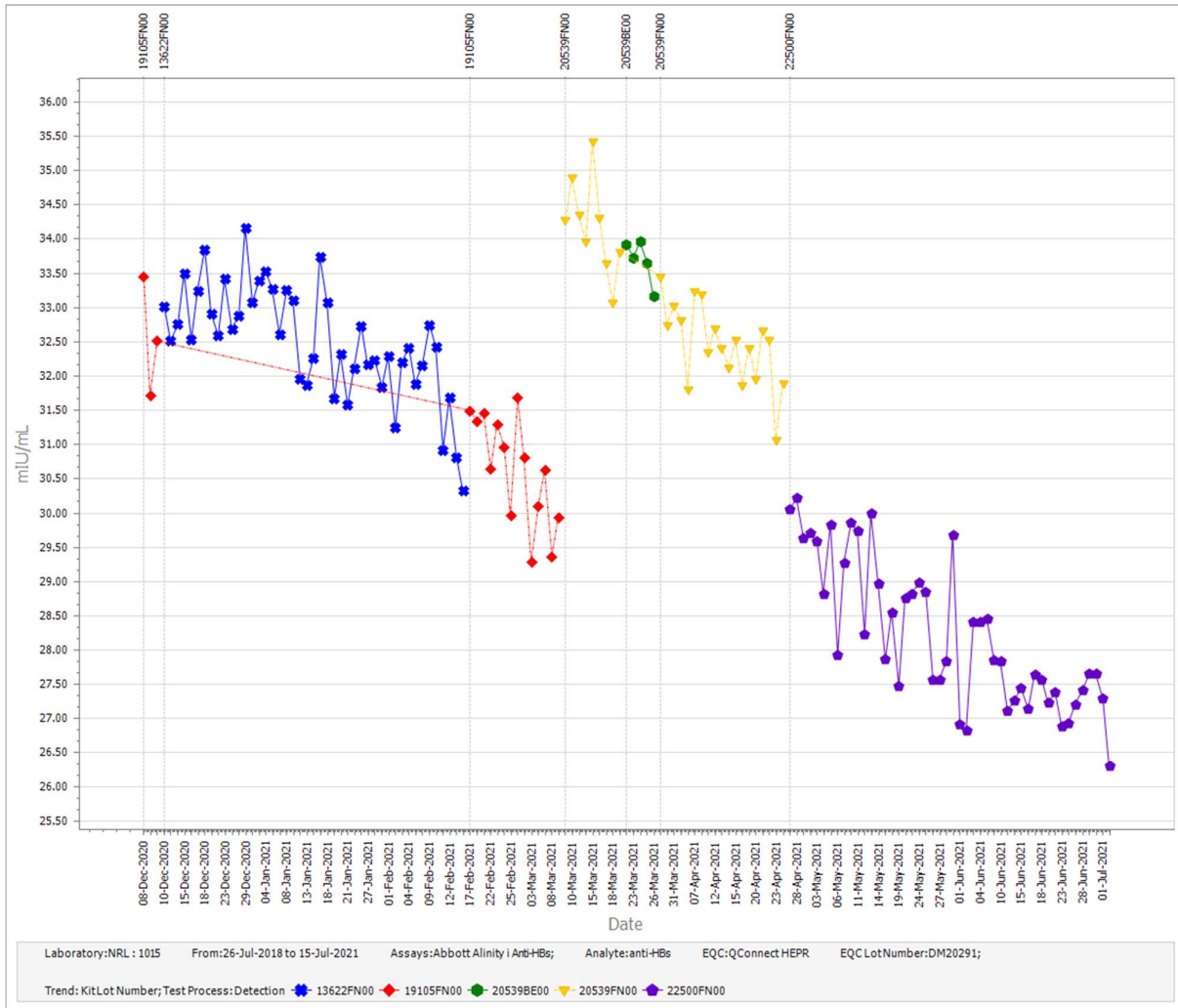


Figure 12 – Participant 1015 data for Abbott Alinity i Anti-HBs; QConnect HEPR lot DM20291 by reagent lot.

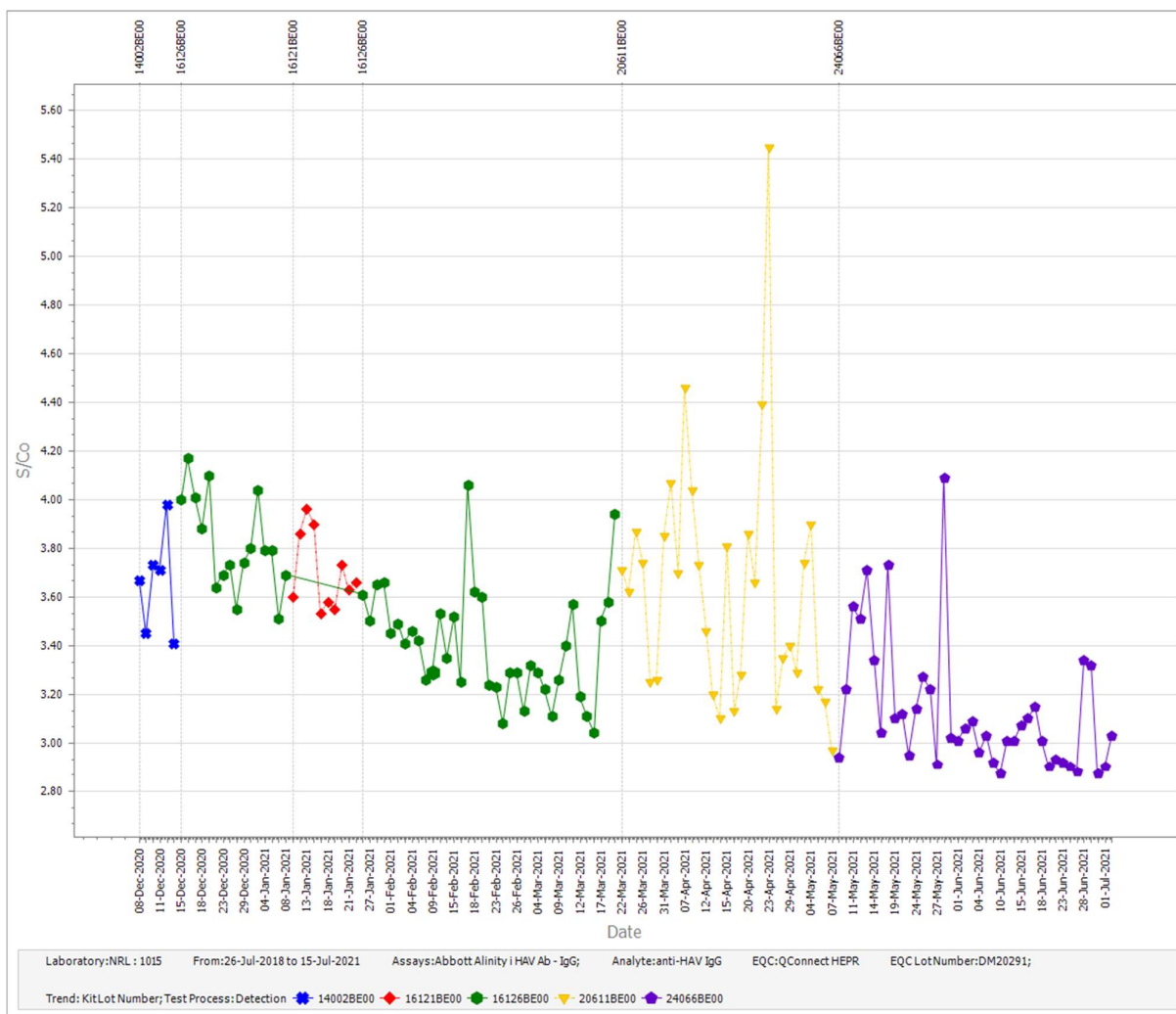


Figure 13 – Participant 1015 data for Abbott Alinity i Anti-HAV Ab IgG; QConnect HEPR lot DM20291 by reagent lot.

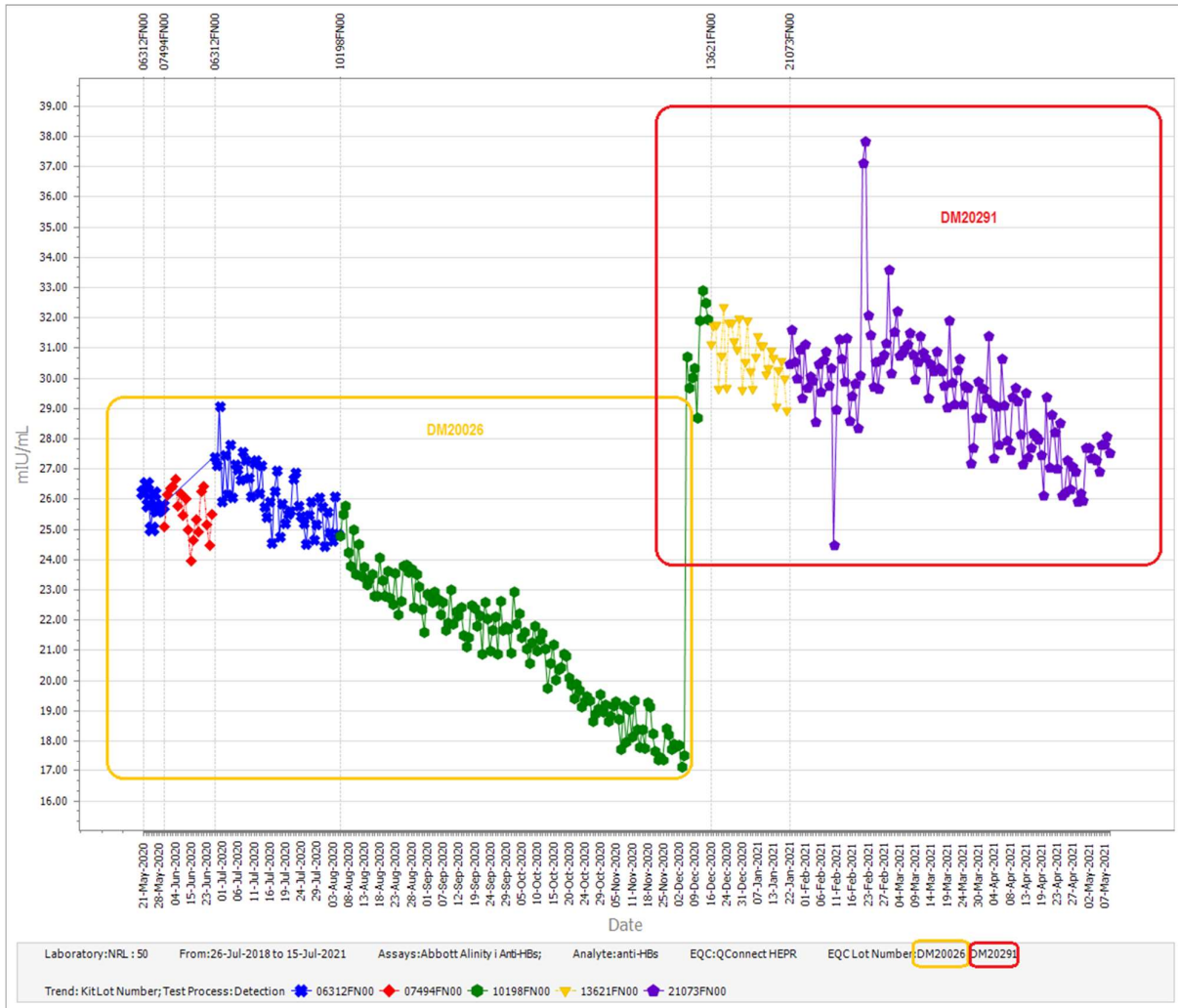


Figure 14 – Participant 50 data for Abbott Alinity i Anti-HBs; QConnect HEPR lots DM20026 and DM20291 by reagent lot.

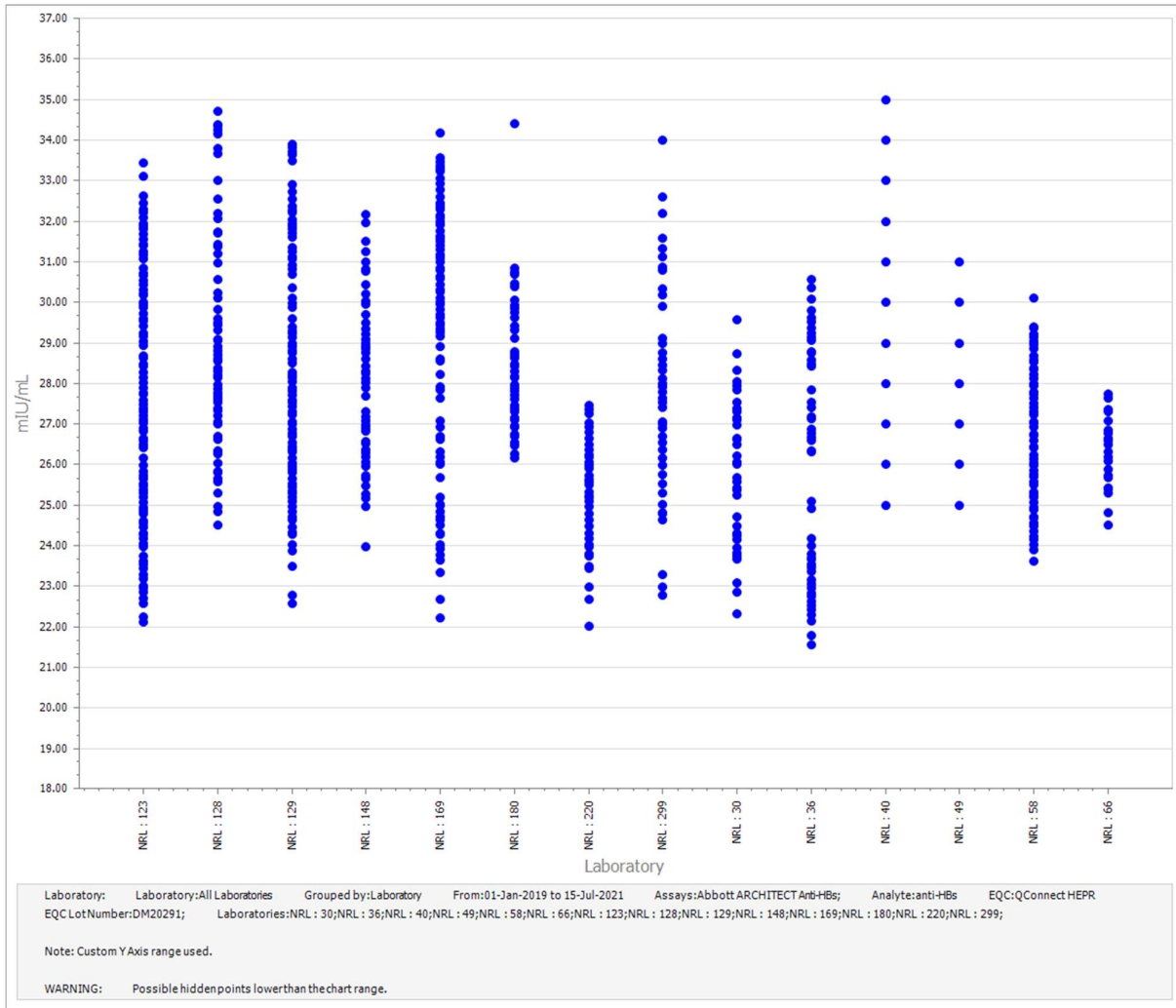


Figure 15 – Peer group data for Abbott ARCHITECT Anti-HBs, QConnect HEPR DM20291.

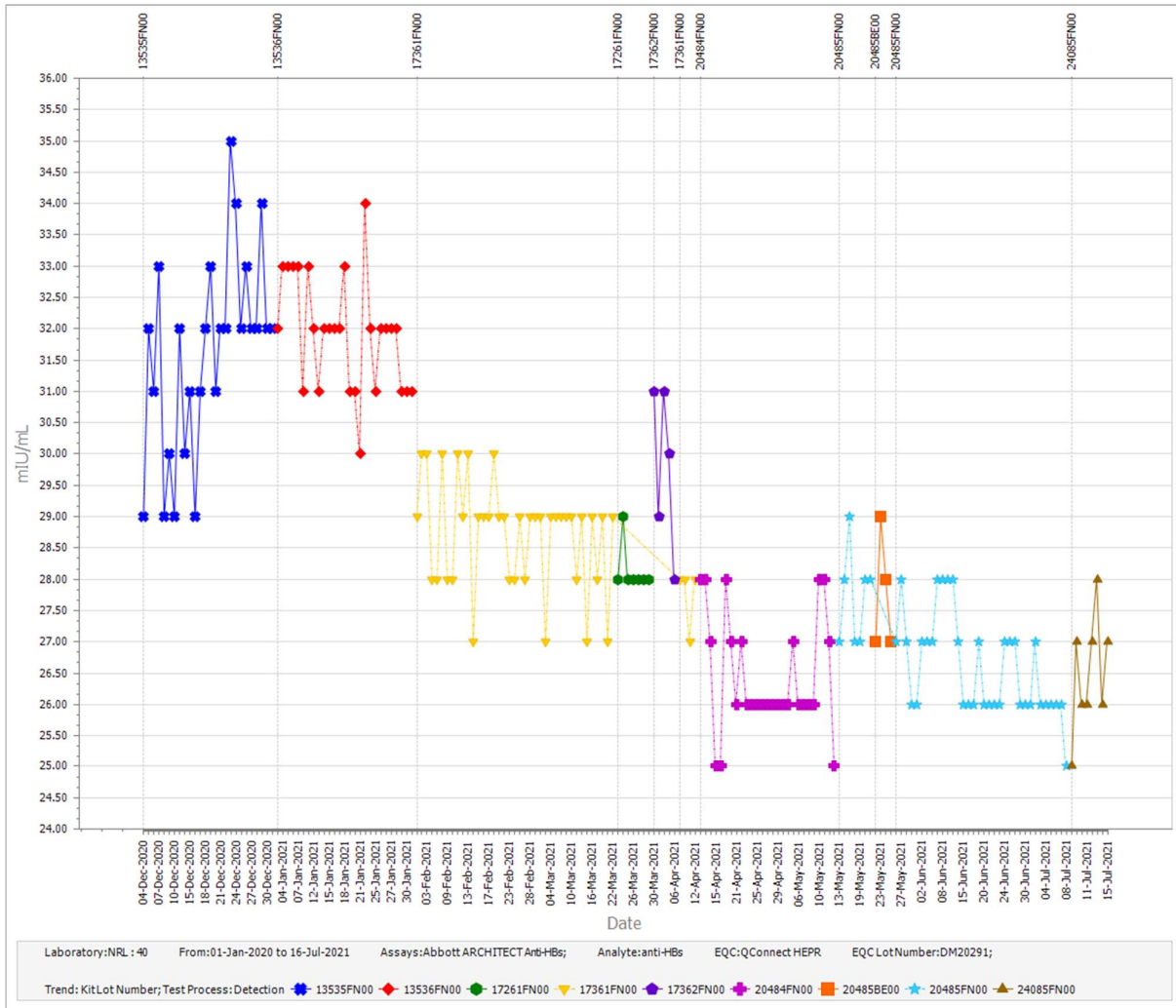


Figure 16 – Participant 40 data for Abbott ARCHITECT Anti-HBs; QConnect HEPR lot DM20291 by reagent lot.

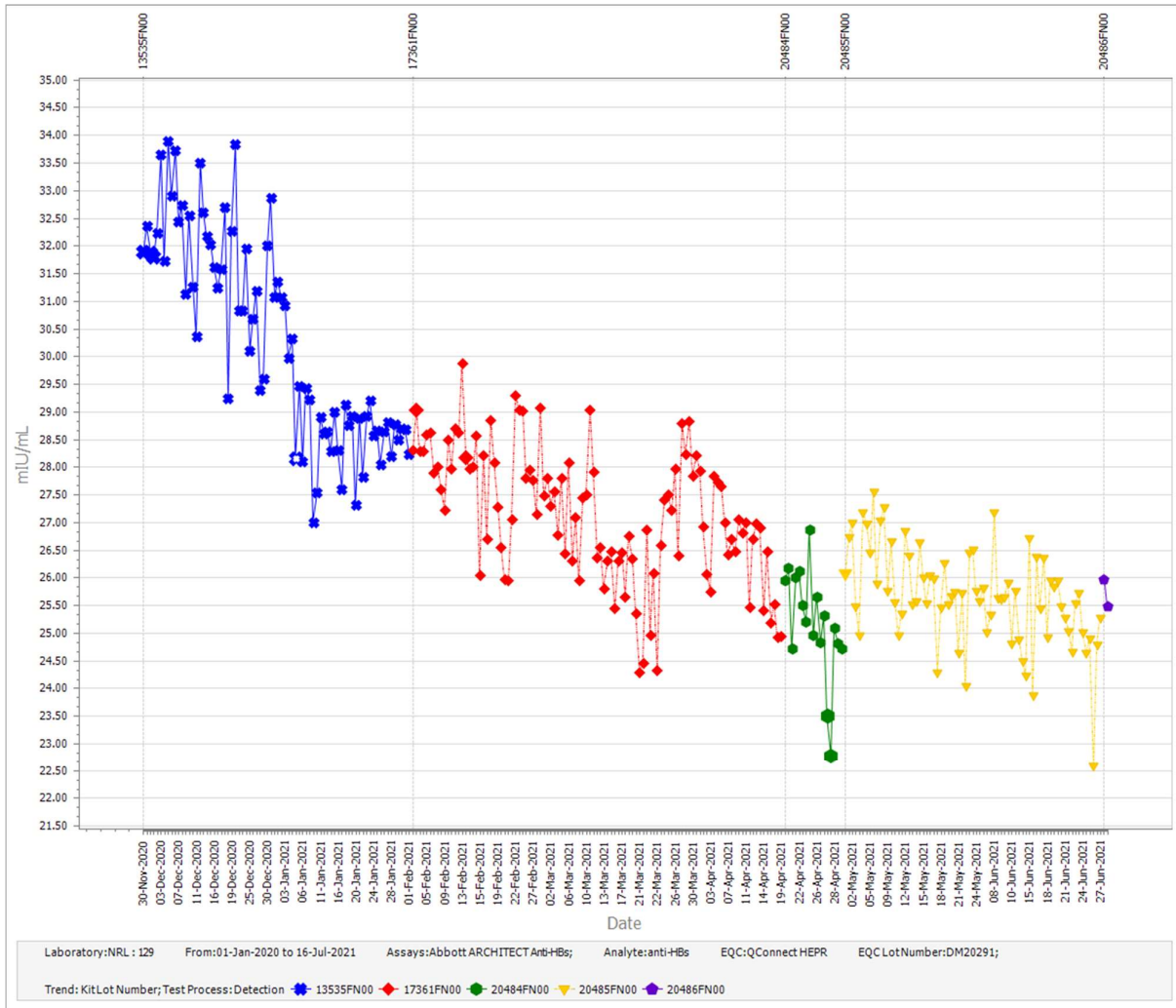


Figure 17- Participant 129 data for Abbott ARCHITECT Anti-HBs; QConnect HEPR lot DM20291 by reagent lot.

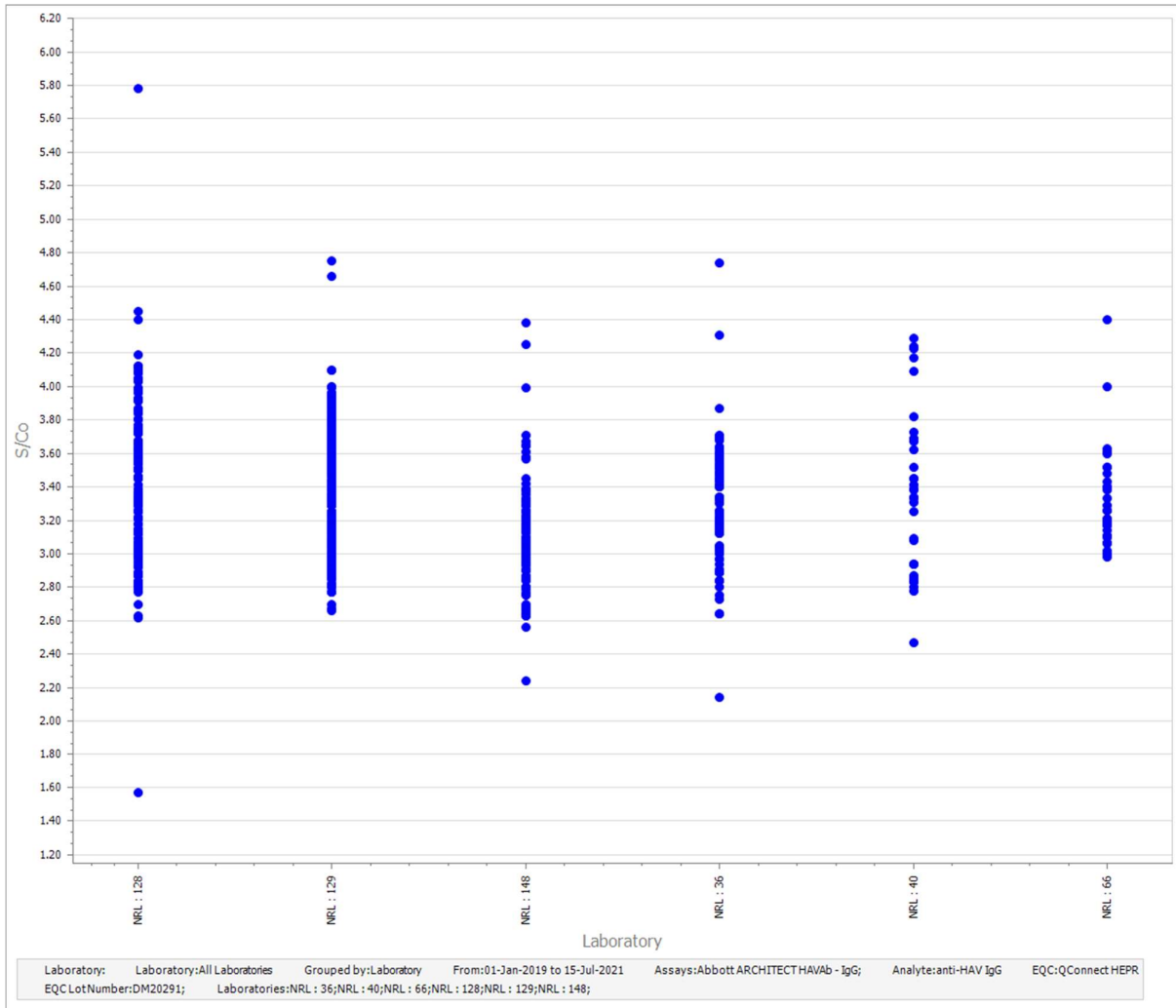


Figure 18 – Peer group data for Abbott ARCHITECT Anti-HAV Ab IgG, QConnect HEPR DM20291.

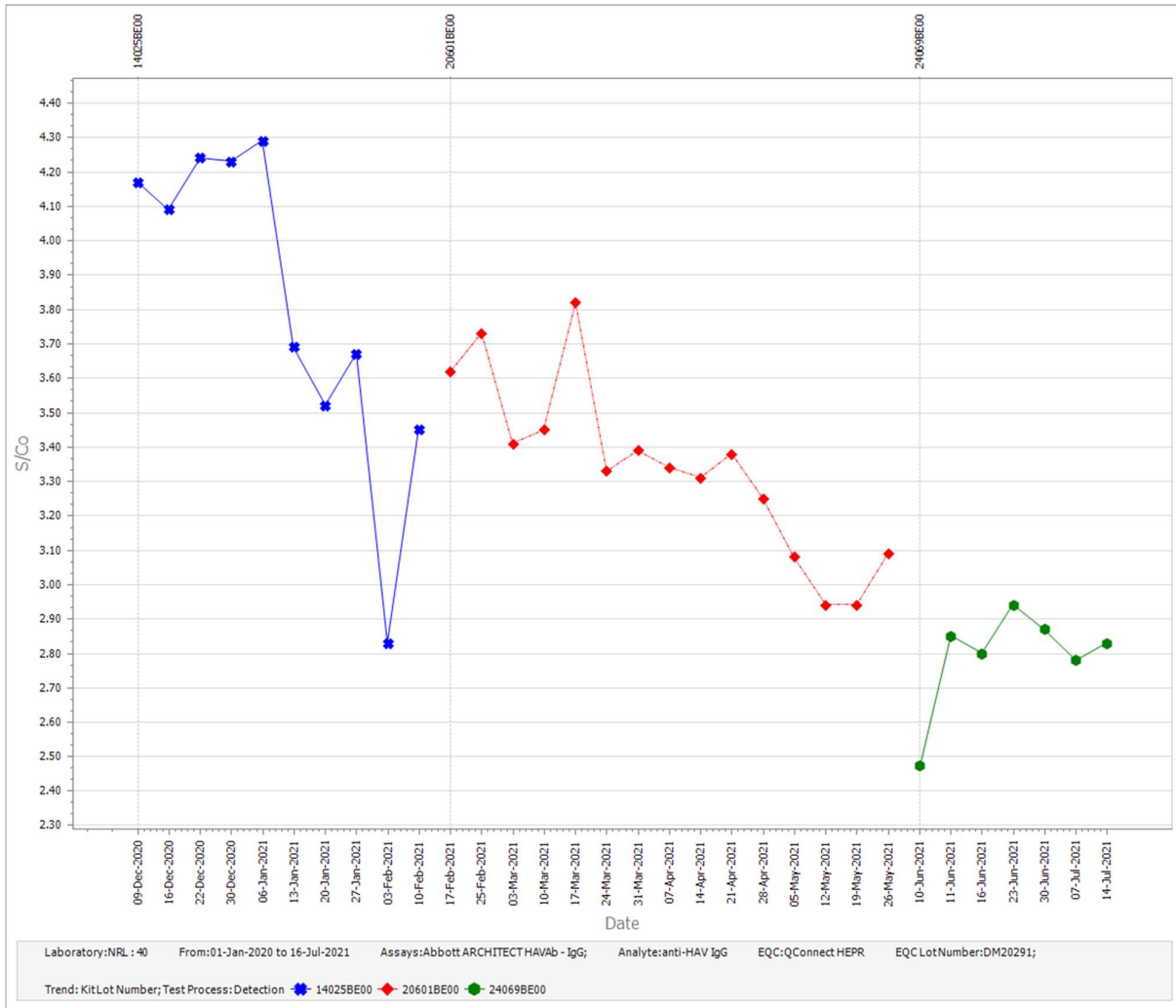


Figure 19 – Participant 40 data for Abbott ARCHITECT Anti-HAVb IgG; QConnect HEPR lot DM20291 by reagent lot.

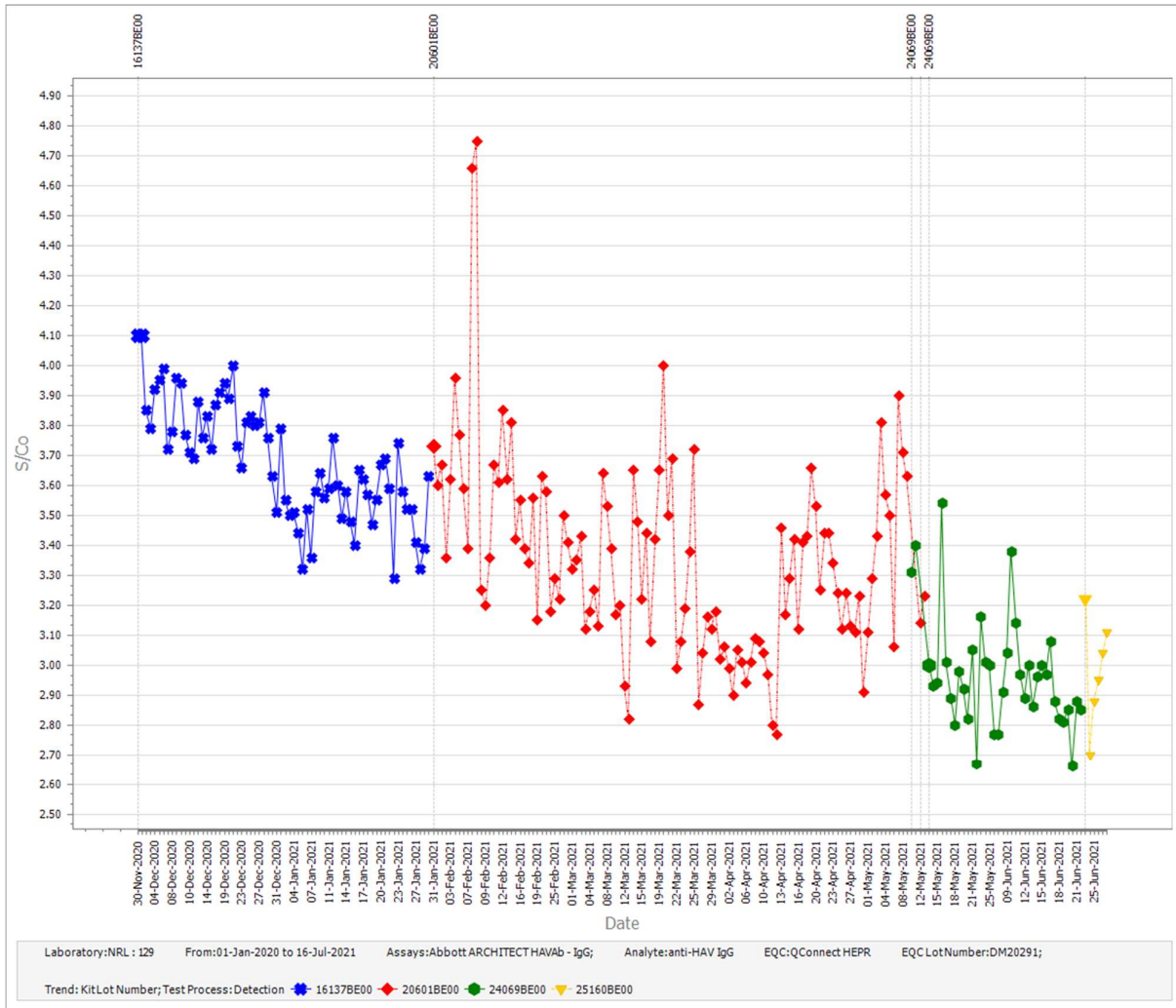


Figure 20 – Participant 129 data for Abbott ARCHITECT Anti-HAVb IgG; QConnect HEPR lot DM20291 by reagent lot.

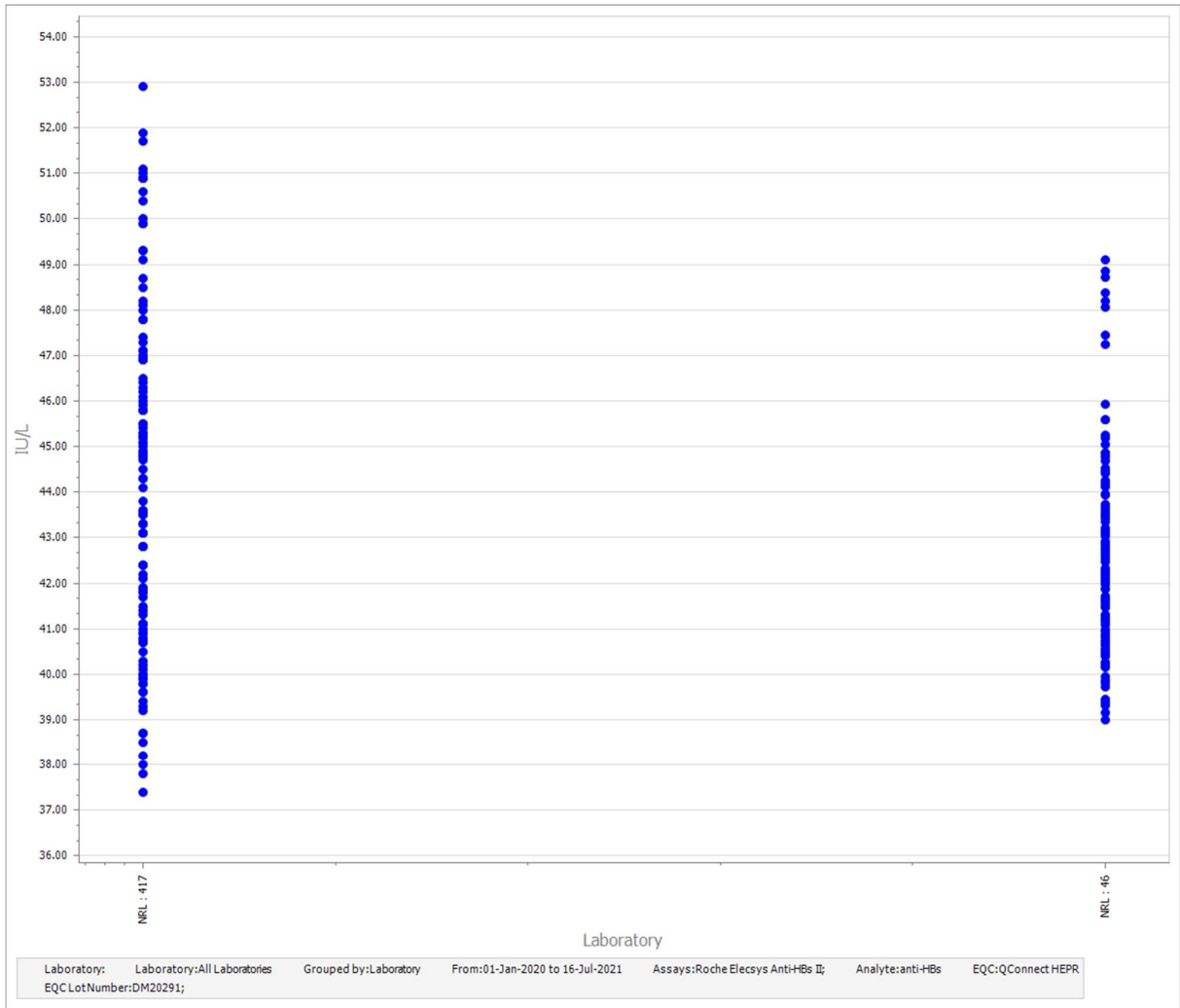


Figure 21 – Peer group data for Roche Elecsys Anti-HBs II, QConnect HEPR DM20291.

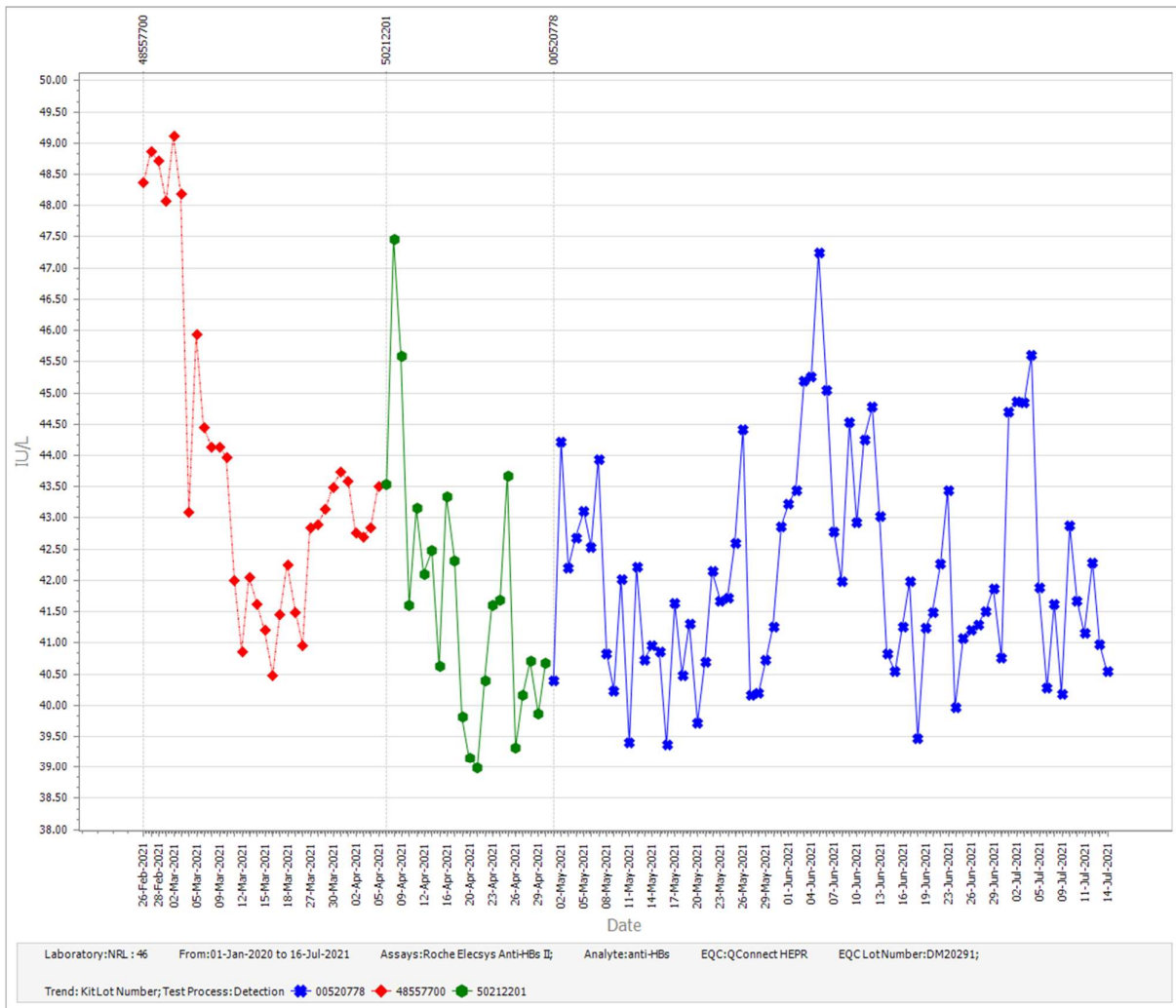


Figure 22 - Participant 46 data for Roche Elecsys Anti-HBs II; QConnect HEPR lot DM20291 by reagent lot.

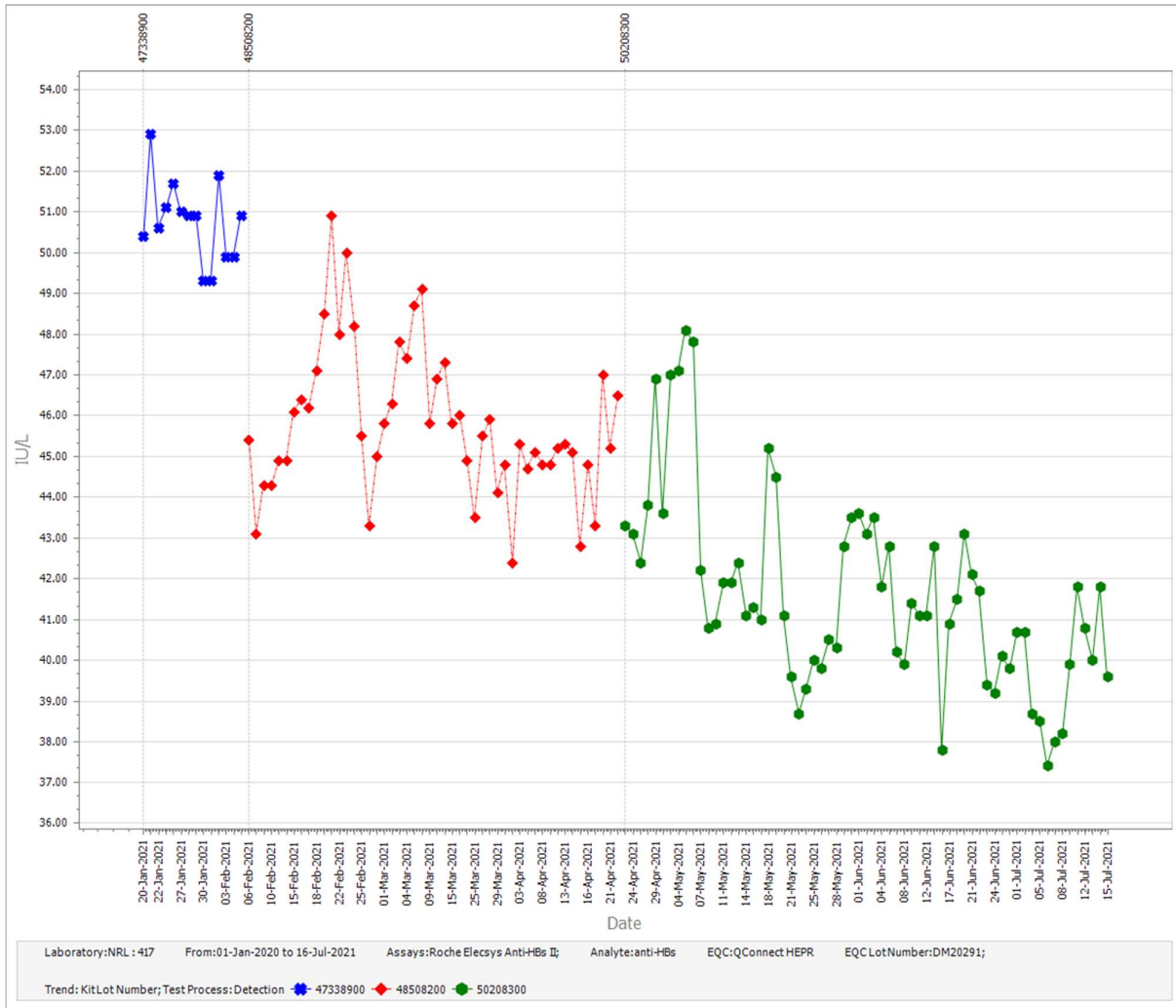


Figure 23 - Participant 46 data for Roche Elecsys Anti-HBs II; QConnect HEPR lot DM20291 by reagent lot.

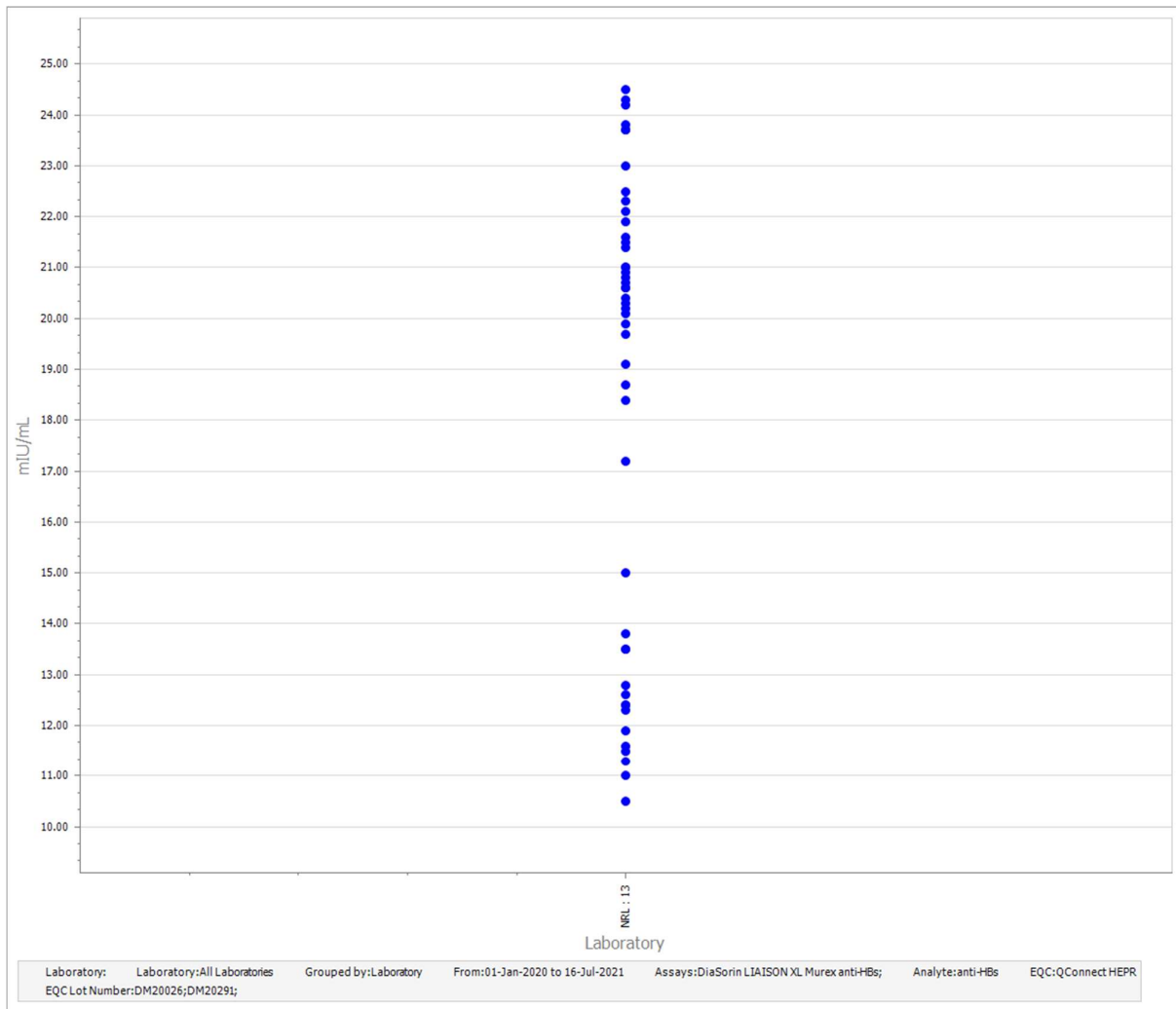


Figure 24 - Peer group data for DiaSorin LIAISON XL Murex anti-HBs, QConnect HEPR DM20291.

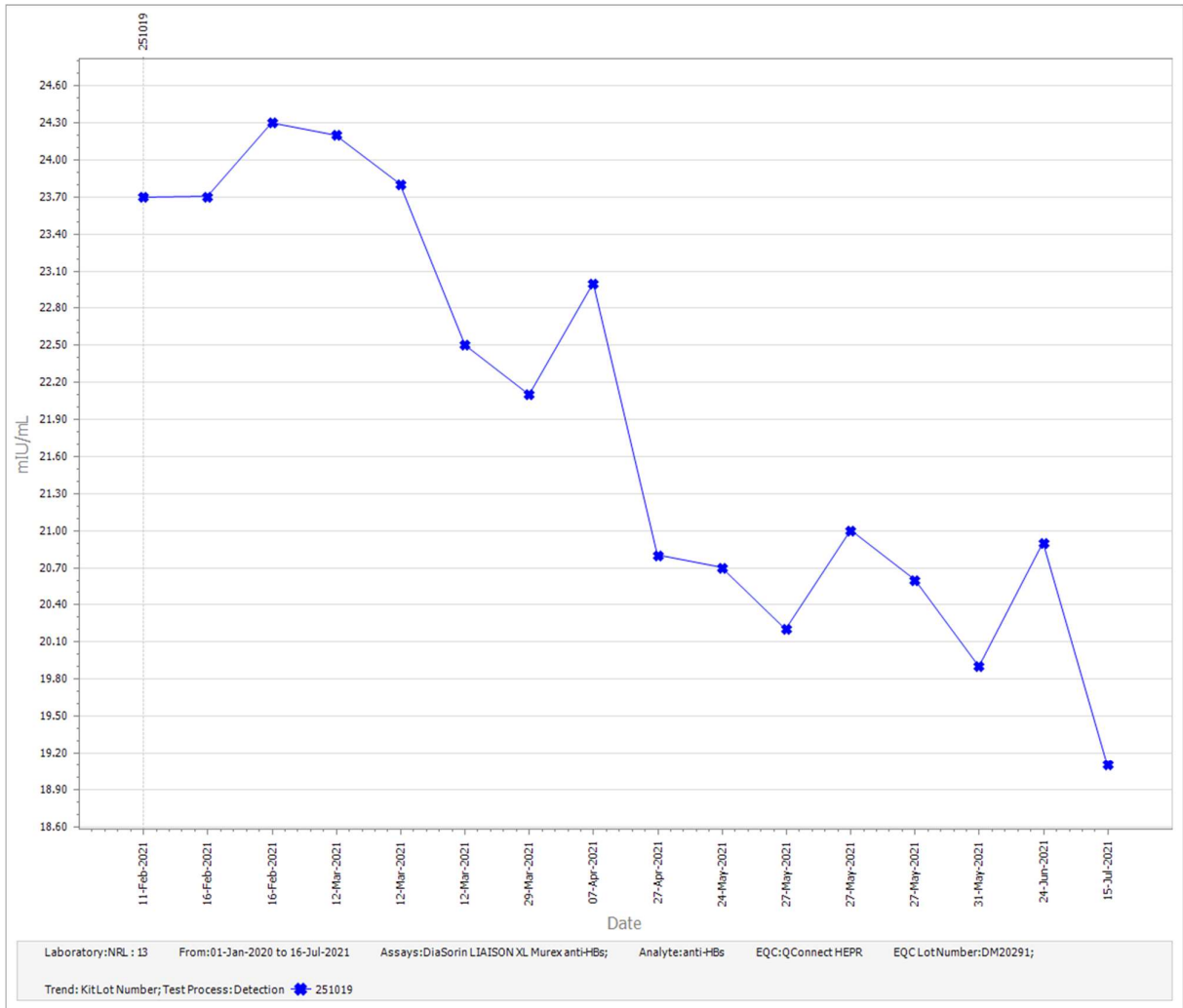


Figure 25 - Participant 13 data for DiaSorin LIAISON XL Murex anti-HBs, QConnect HEPR DM20291.