



# **QC SEROLOGY INVESTIGATION PMM-QC-794**

**NRL is:**

- Accredited by NATA as a Medical Testing Laboratory compliant with ISO 15189;
- Accredited by NATA as a Proficiency Testing Provider compliant with ISO 17043, with NATA Accreditation Number 14253;
- Licenced by the Therapeutic Goods Administration as compliant with the Code of Good Manufacturing Practice;
- Certified by BSI for Quality Management, as compliant with ISO 9001;
- Certified by BSI for Safety Management, as compliant with AS/NZS 4801;
- A World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.

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**Date: 23/11/2020**



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## 1 Introduction

NRL was contacted by participants 129 and 145 regarding the occurrence of random drops in data results, some falling below the lower QConnect range, for QConnect HIV p24, DM19142 on the Abbott ARCHITECT HIV Ab/Ag Combo assay.

## 2 Findings

Figure 1: Peer Group data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by participant.

Figure 2: Peer Group data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 3: Peer Group data for Positive Kit control, Viral Lysate for Abbott ARCHITECT HIV Ag/Ab Combo by participant.

Figure 4: Peer Group data for Positive Kit control, Viral Lysate for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 5: Participant 129 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 6: Participant 145 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 7: Participant 12 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 8: Participant 123 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 9: Participant 148 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 10: Participant 169 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 11: Participant 176 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 12: Participant 183 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 13: Participant 30 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 14: Participant 36 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 15: Participant 49 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 16: Participant 58 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 17: Participant 8 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 18: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by laboratory.

Figure 19: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 20: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lots that are common with DM19142 usage.

Figure 21: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by Laboratory.

Figure 22: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

Figure 23: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lots that are common with DM19142 usage.

Figure 24: Peer Group data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by laboratory.

Figure 25: Peer Group data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

Figure 26: Participant 1015 data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

Figure 27: Participant 50 data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

Figure 28: Peer Group data for QConnect HIVp24, DM19027, for Abbott Alinity i HIV Ag/Ab Combo by laboratory.

Figure 29: Peer Group data for QConnect HIVp24, DM19027, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

Table 1: Ordering and shipping information for QConnect HIVp24 DM19142, provided by NRL administration and LFS.

### 3 Discussion

When investigating Participants 129 and 145 drops in results for the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect HIVp24 DM19142, data from all available QC material, both EQC and kit controls from all participants in the peer group were investigated to establish whether there was any evidence of trends or patterns across the peer group or QC materials.

Figures one and two show peer group data for the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect HIVp24 DM19142. Seven participants recorded data below QConnect limits (2.20 – 5.60 S/Co) across eight reagent lots, and two participants recorded data below the assay cut off (<1.00 S/Co) across three reagent lots.

Figures three and four show peer group data for the Abbot ARCHITECT HIV Ab/Ag Combo assay for Positive Kit control, Viral Lysate. All data recorded were constant across the peer group and reagent lots, with no entries below the assay cut off (<1.00 S/Co).

As can be seen in figure two there were eight reagent lots where drops in data values were recorded. These reagent lots, 13157BE00, , 13456BE00, 14241BE00, 15195BE00, 16397BE00, 16595BE00 and 17336BE00, were reviewed further, reviewing data reported for both older and newer QC lots to establish if the pattern of random drops in data was observed in any other QC lot.

Figures 19 and 20 illustrate peer group data for the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect HIVp24 DM19027 (the previous QC lot, expiry date April 2021). Seven of the previously mentioned reagent lots were in use, only reagent lot 16397BE00 had no data recorded for this QC lot. The data recorded for the seven reagent

lots in common usage with QConnect DM19142, showed no random drops in data and no data were recorded below QConnect limits or Assay cut-off.

Figures 22 and 23 illustrate peer group data for the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect HIVp24 DM20115 (the current QC lot, expiry date March 2022). Only one of the previously mentioned reagent lot (13456BE00) was in use, for this QC lot. The data recorded for this reagent lot showed no random drops in data and no data were recorded below QConnect limits or the Assay cut-off.

Due to the variation and inconsistency observed both within and between participants, illustrated in figures 1 to 17, in which no pattern or trend could be identified NRL requested and received shipping and tracking information from LFS for review (Table 1). The data received showed no delay in packing, shipping and delivery for orders of QConnect HIVp24, DM19142, and no shipping issues were recorded by LFS or participants on receipt of goods.

The variation and random drops in data observed on the Abbott ARCHITECT HIV Ag/Ab Combo assay testing with QConnect HIVp24; DM19142, was also observed on the Abbott Alinity i HIV Ag/Ab Combo, QConnect HIVp24; DM19142 (Figures 24 to 27).

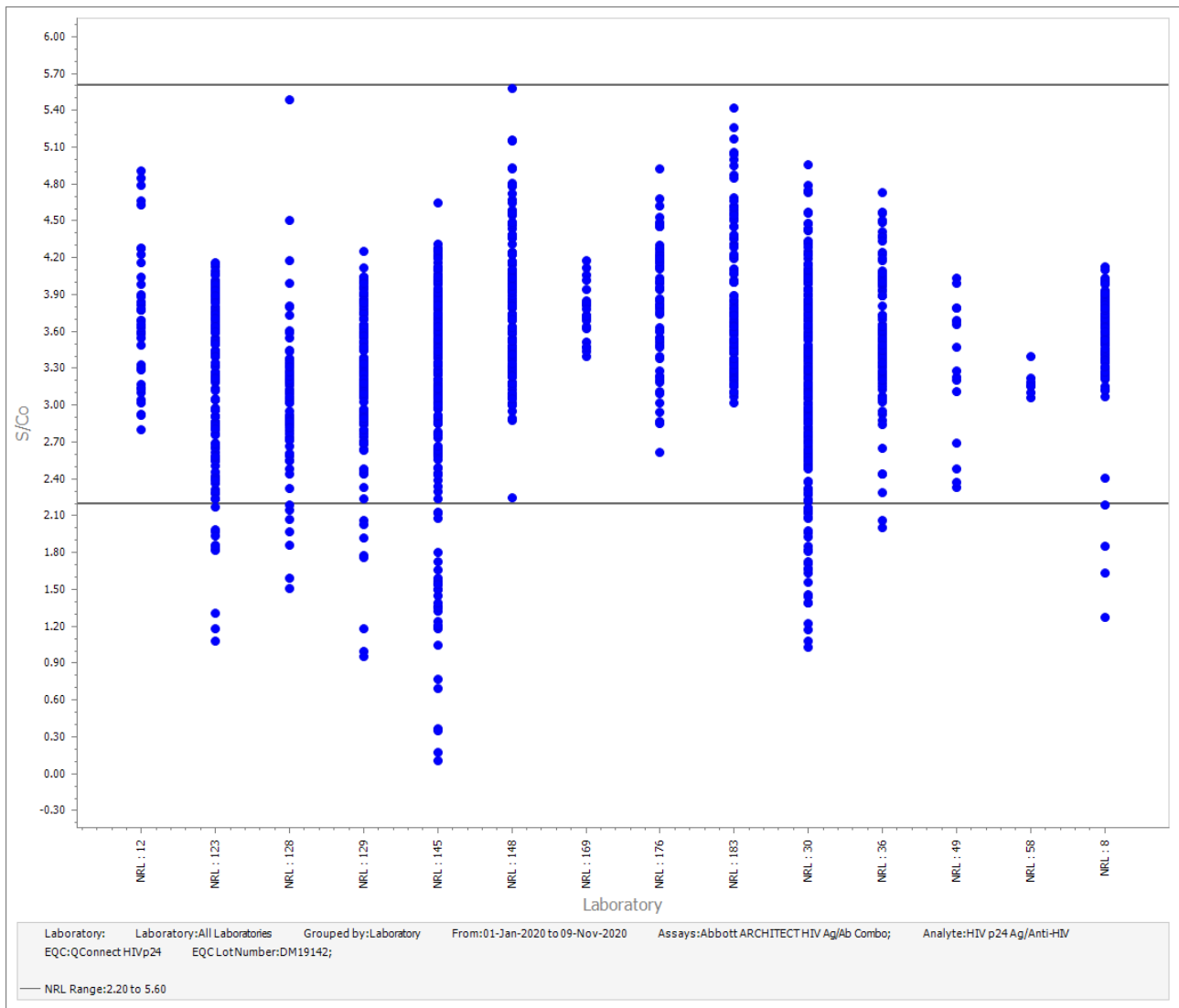


Figure 3: Peer Group data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by participant.

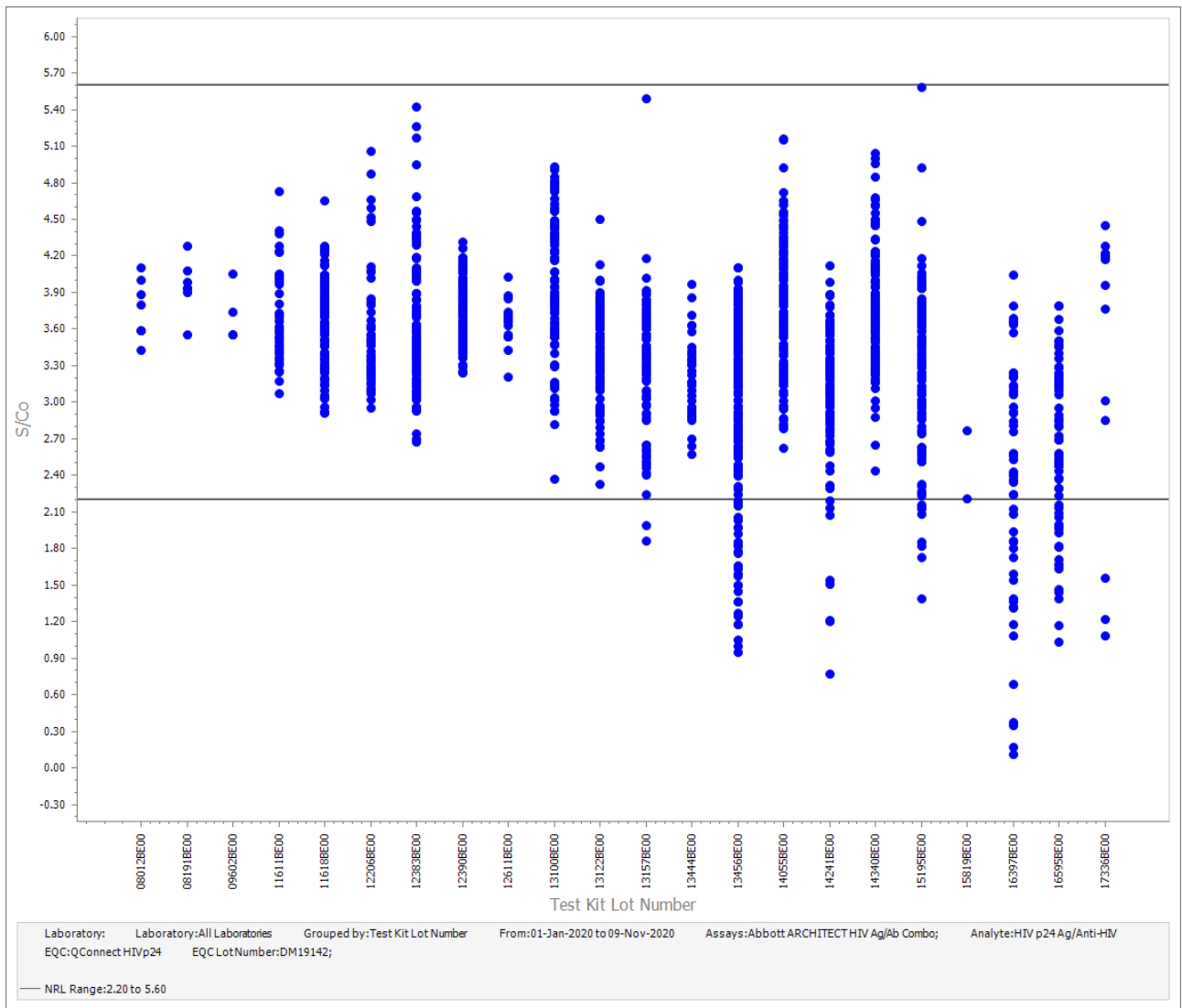


Figure 4: Peer Group data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.



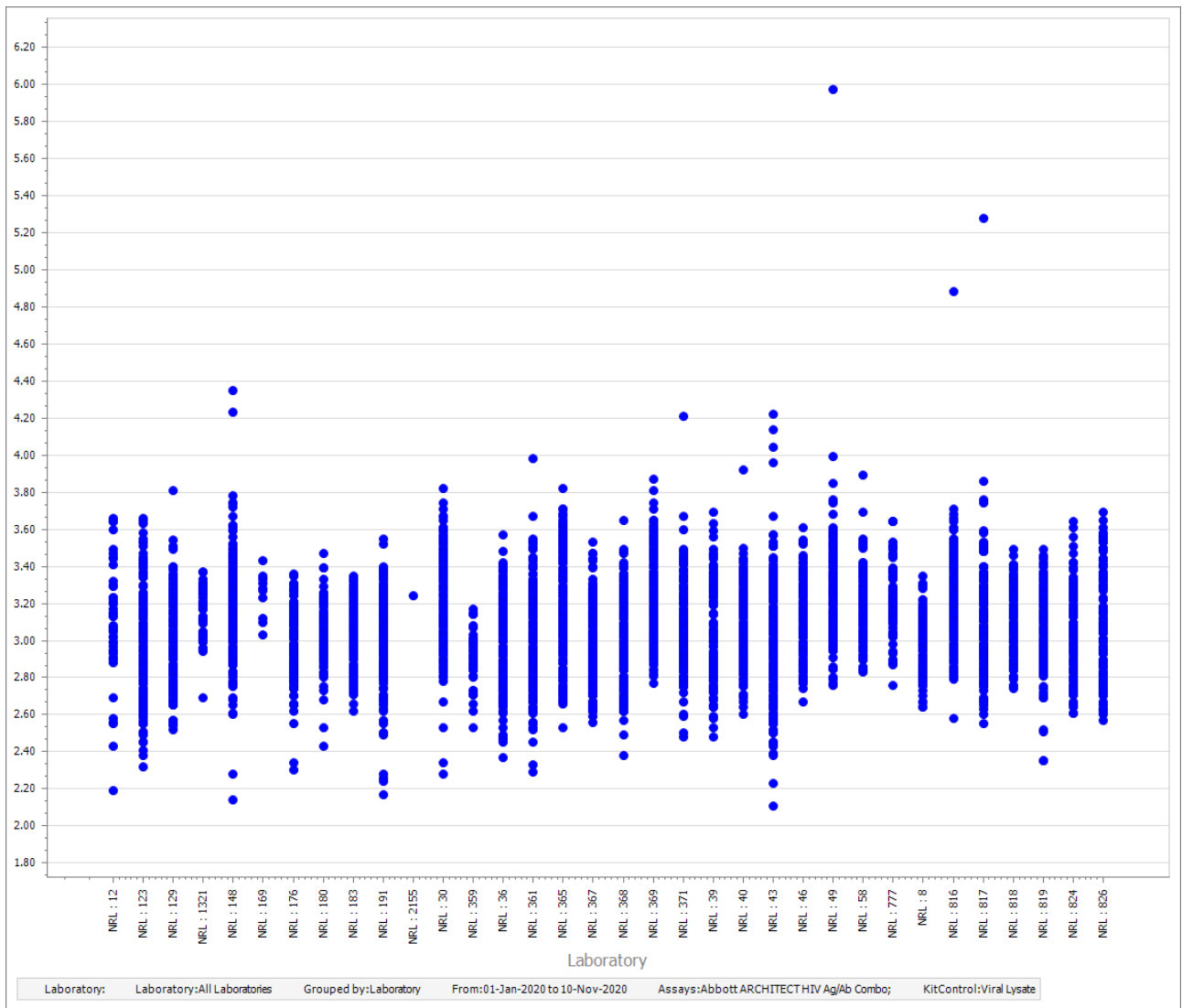


Figure 3: Peer Group data for Positive Kit control, Viral Lysate for Abbott ARCHITECT HIV Ag/Ab Combo by participant.

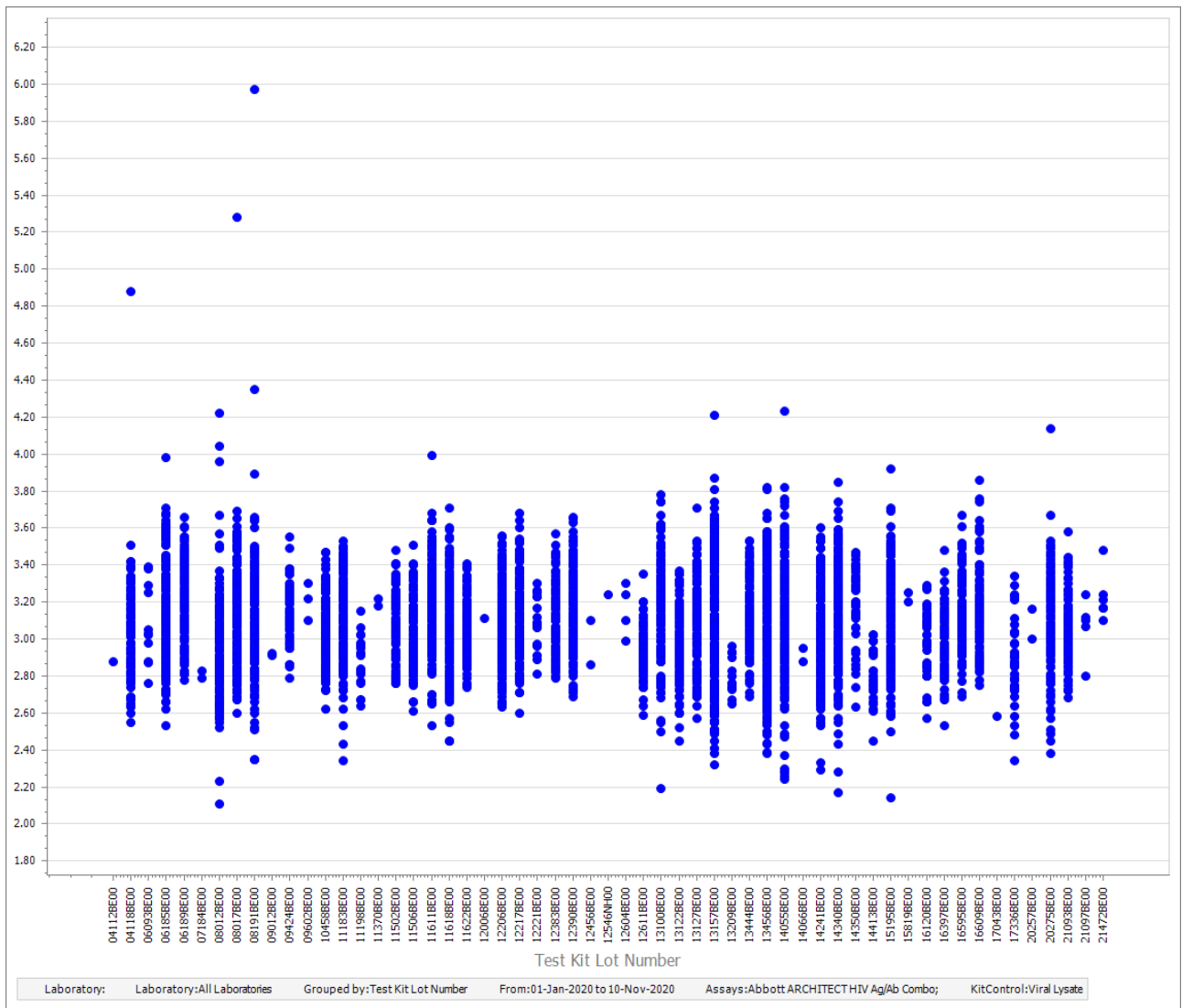


Figure 4: Peer Group data for Positive Kit control, Viral Lysate for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

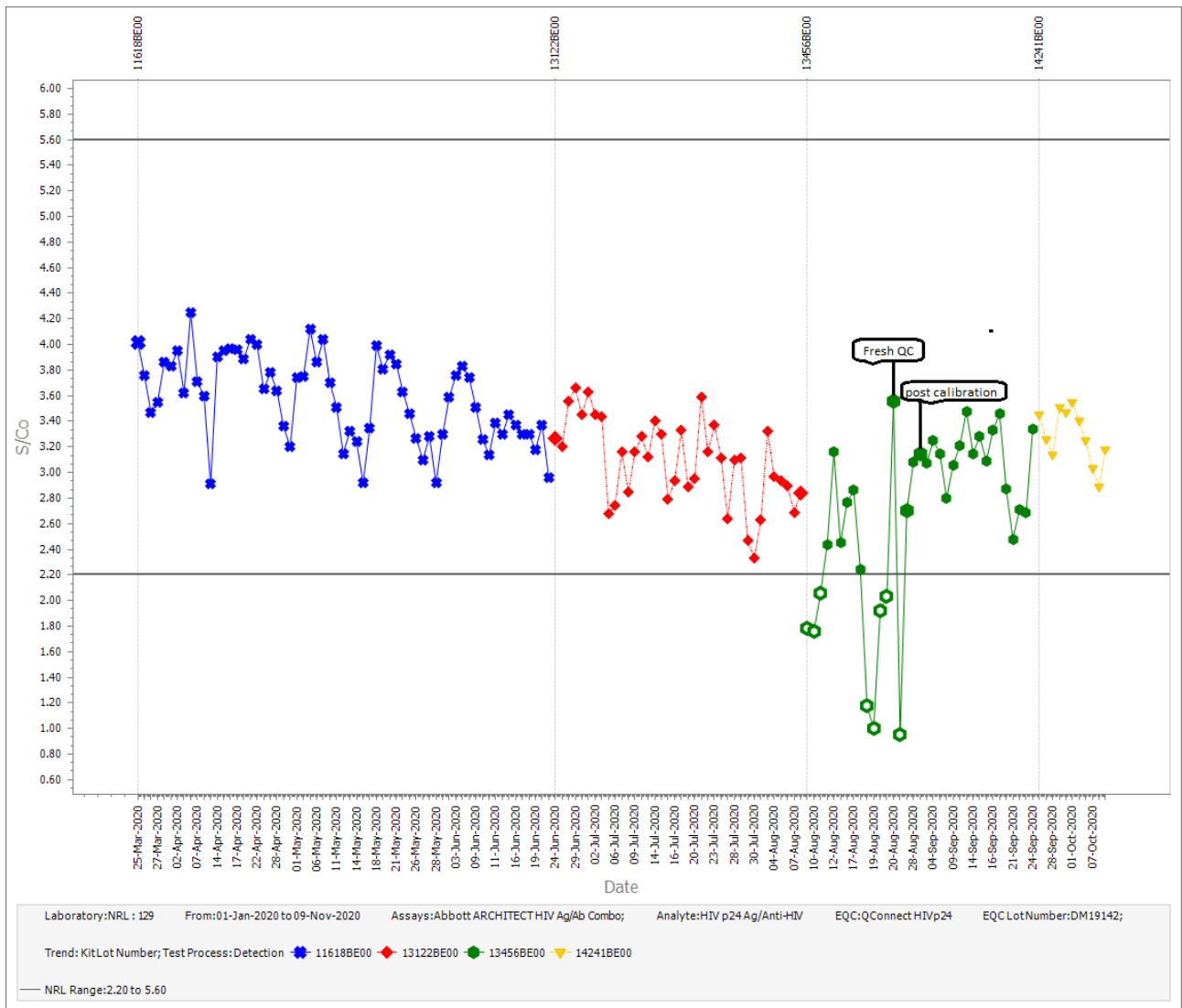


Figure 5: Participant 129 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

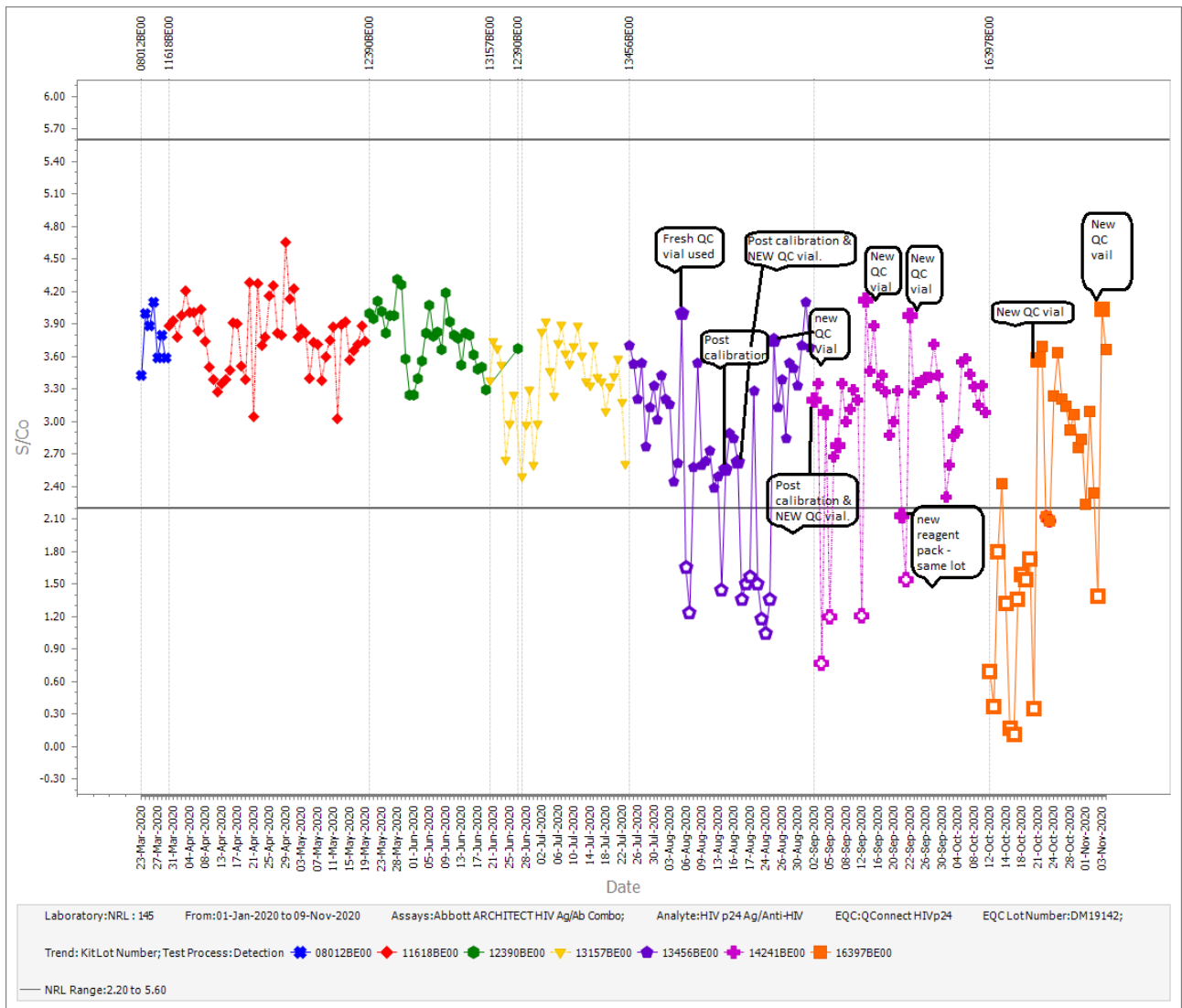


Figure 6: Participant 145 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

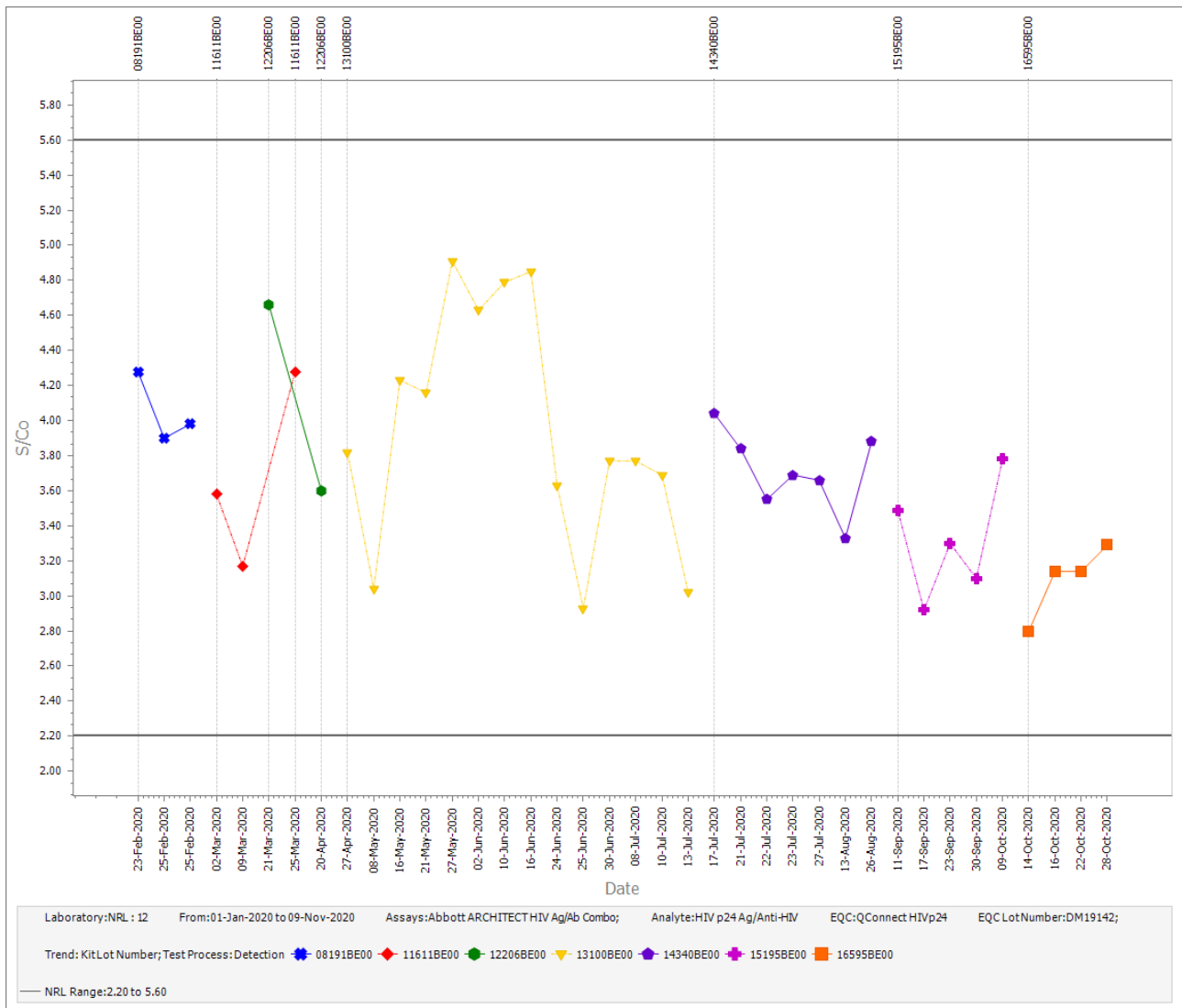


Figure 7: Participant 12 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

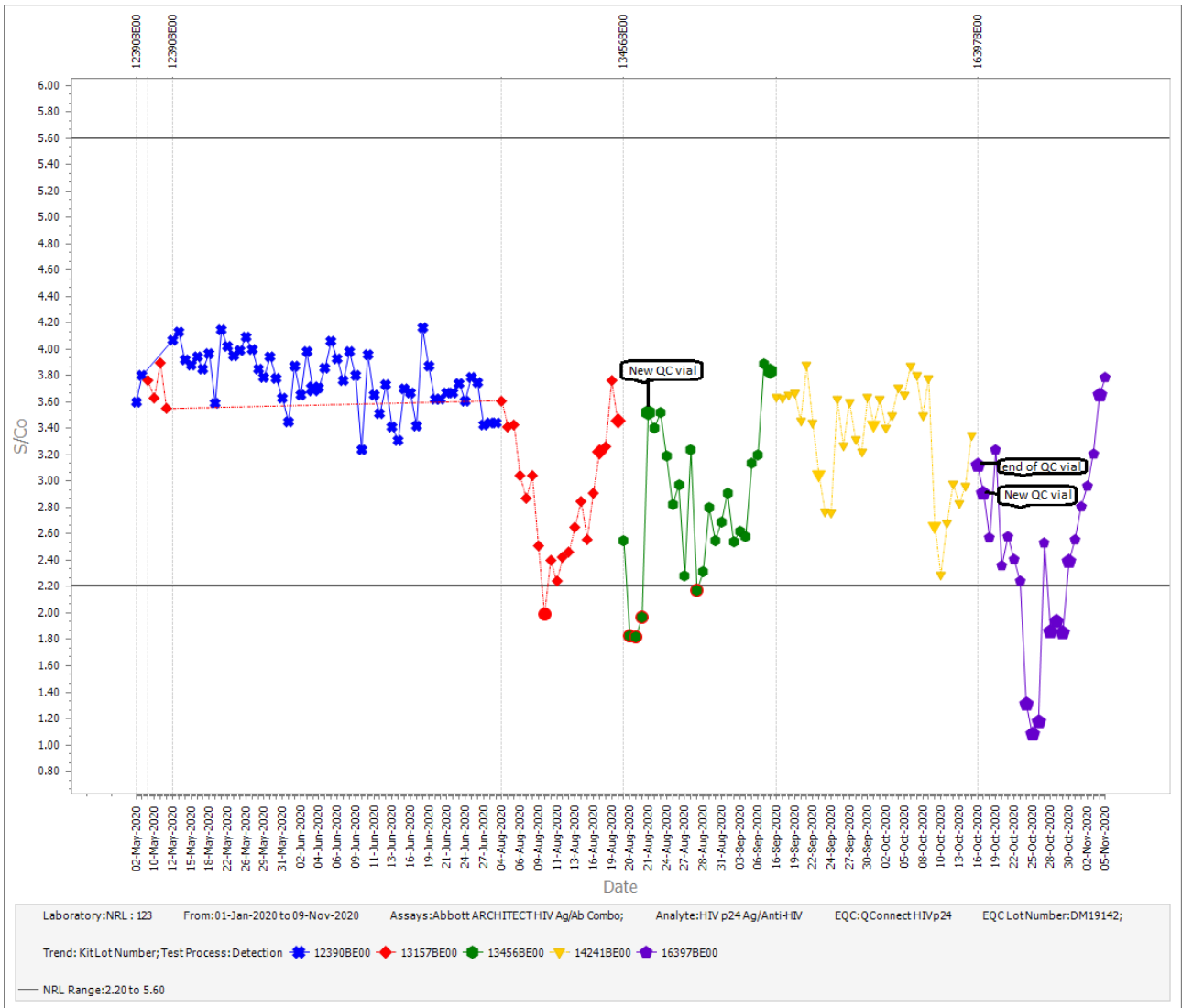


Figure 8: Participant 123 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

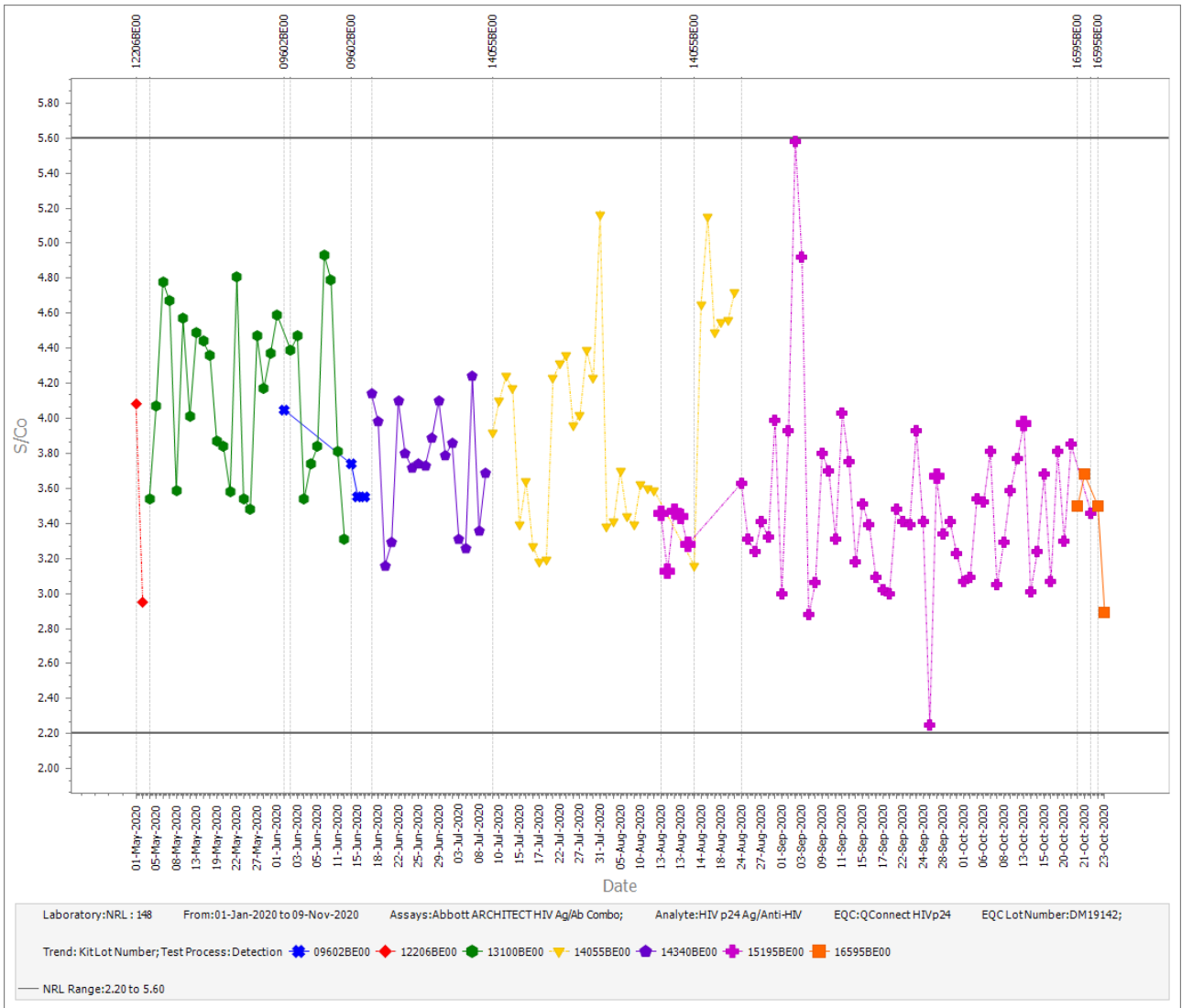


Figure 9: Participant 148 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

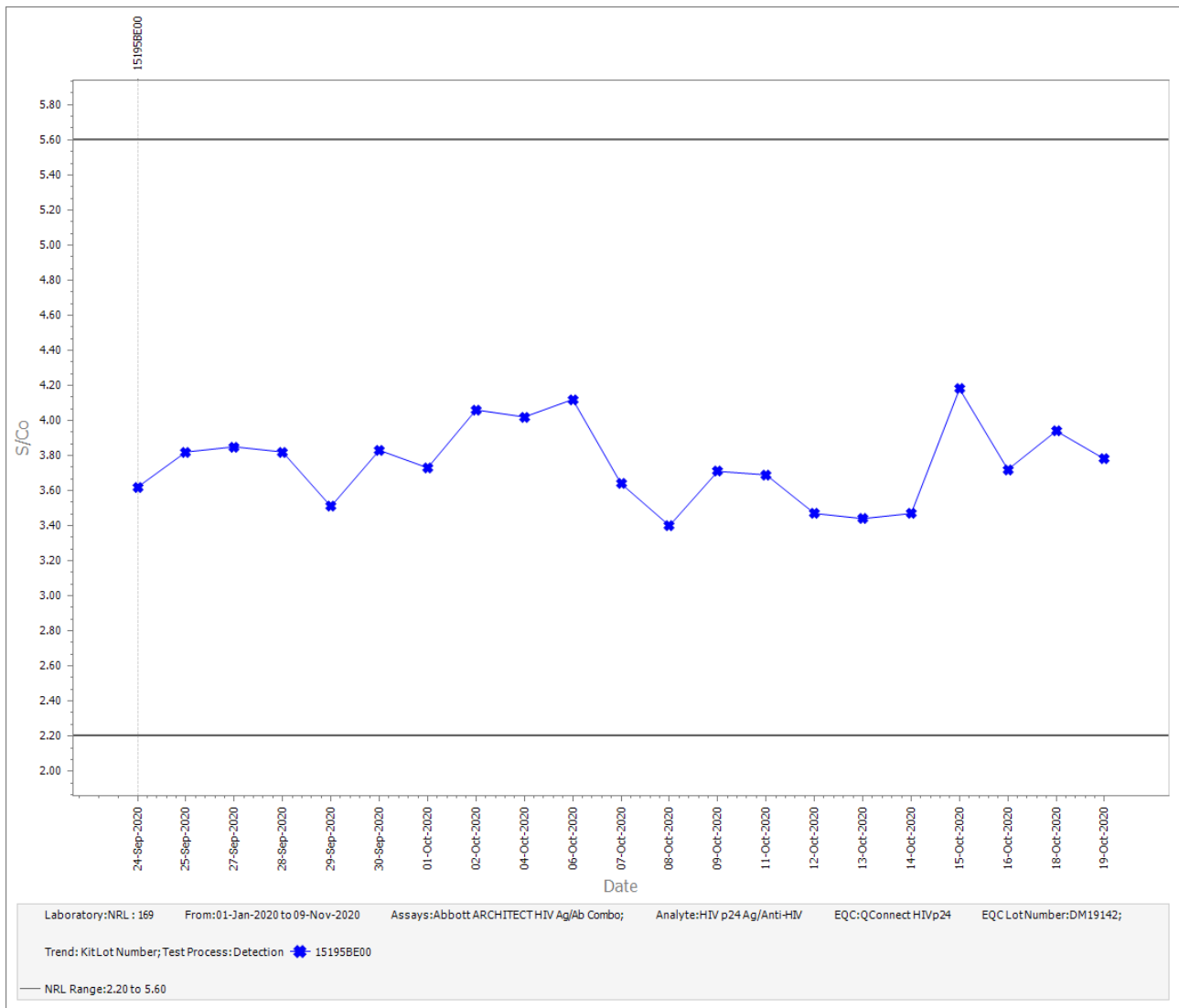


Figure 10: Participant 169 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.



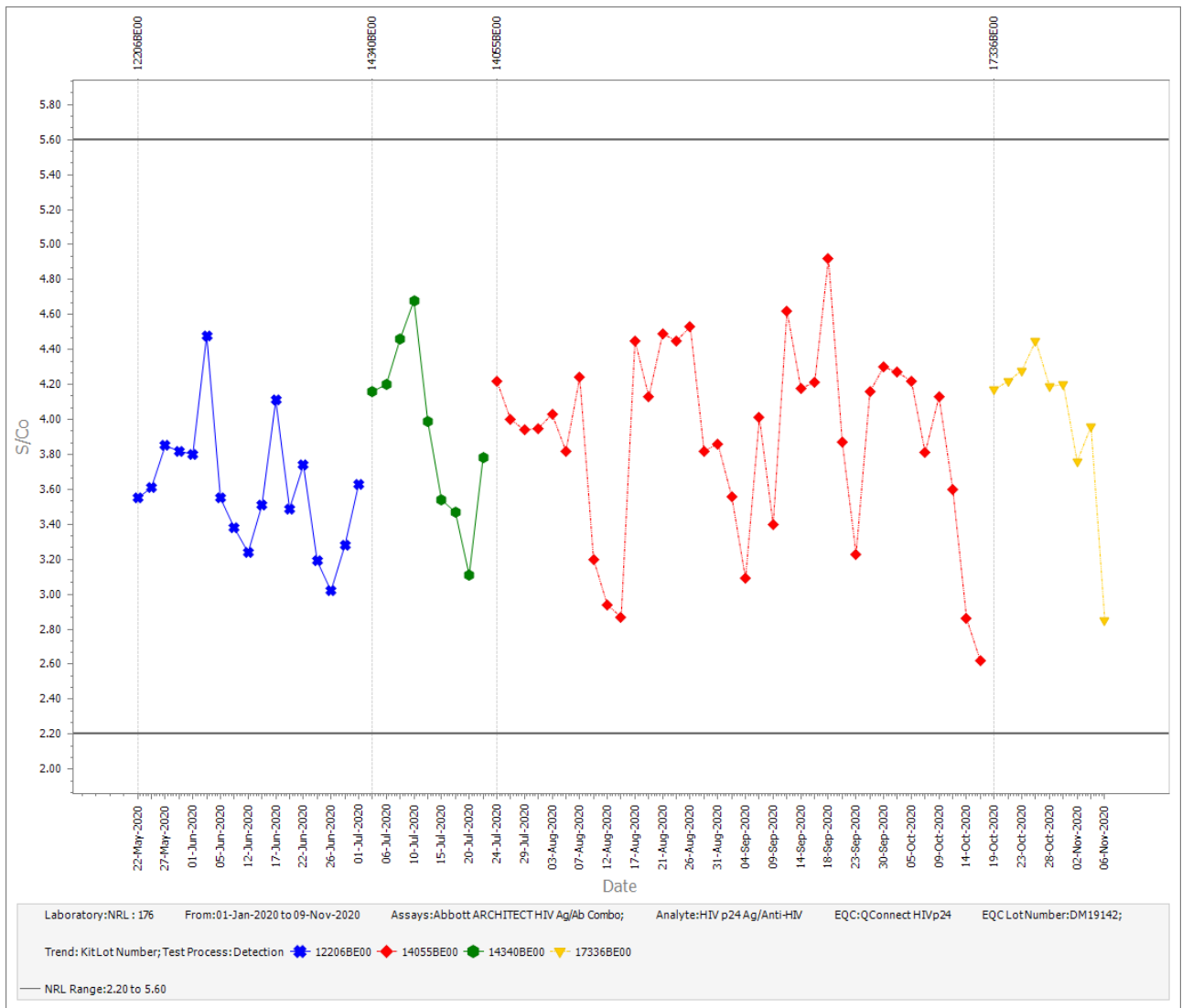


Figure 11: Participant 176 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

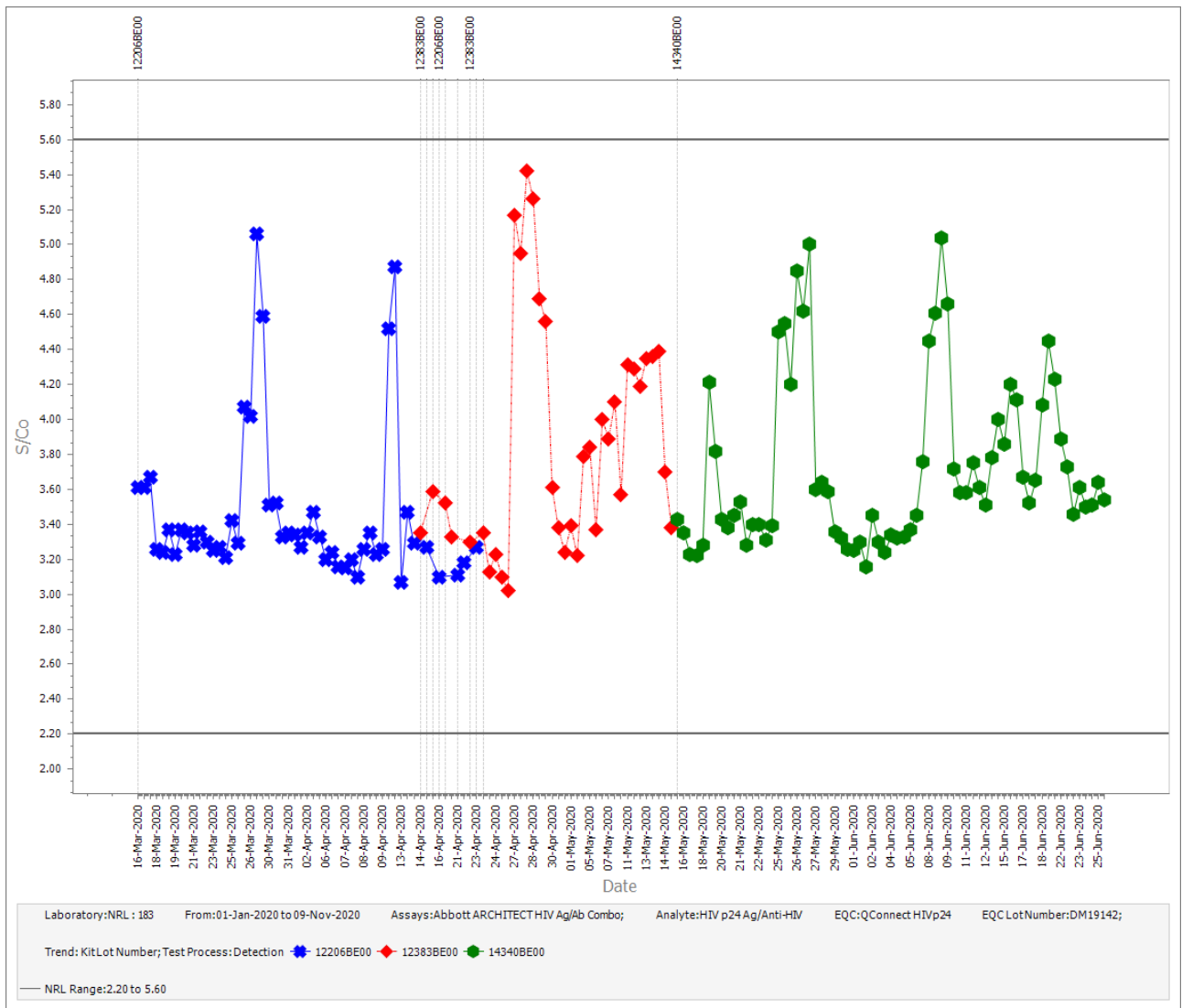


Figure 12: Participant 183 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

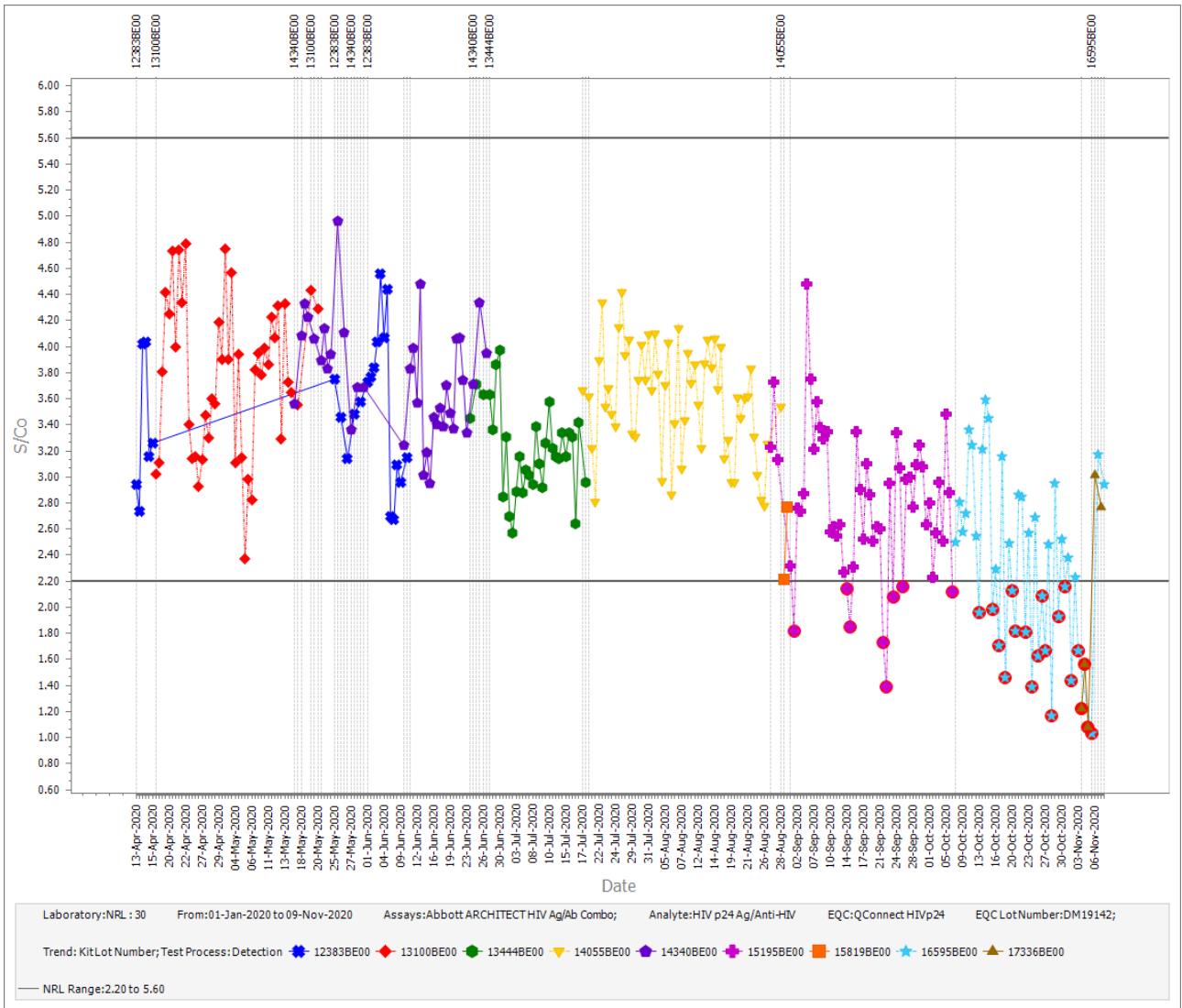


Figure 13: Participant 30 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

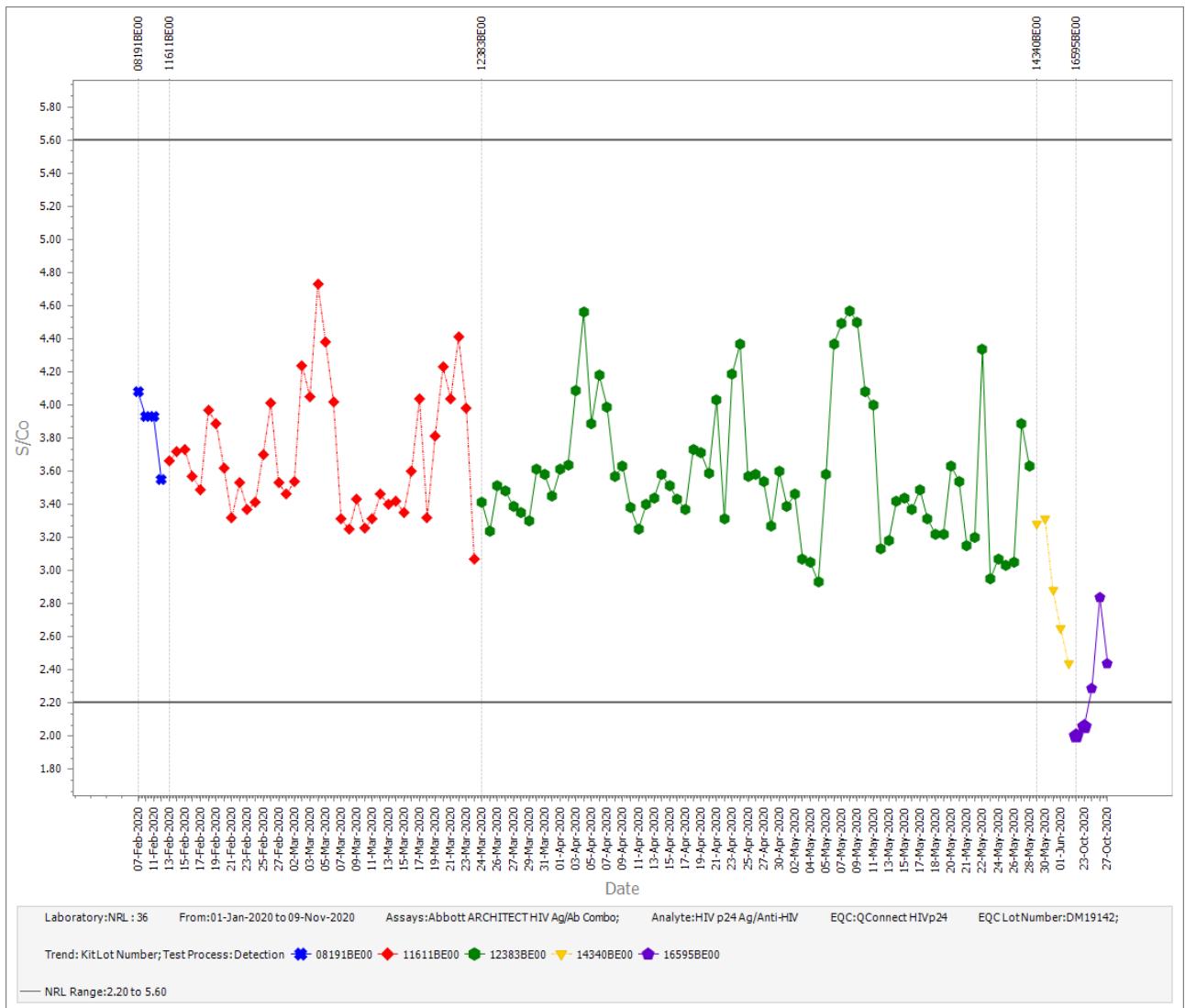


Figure 14: Participant 36 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

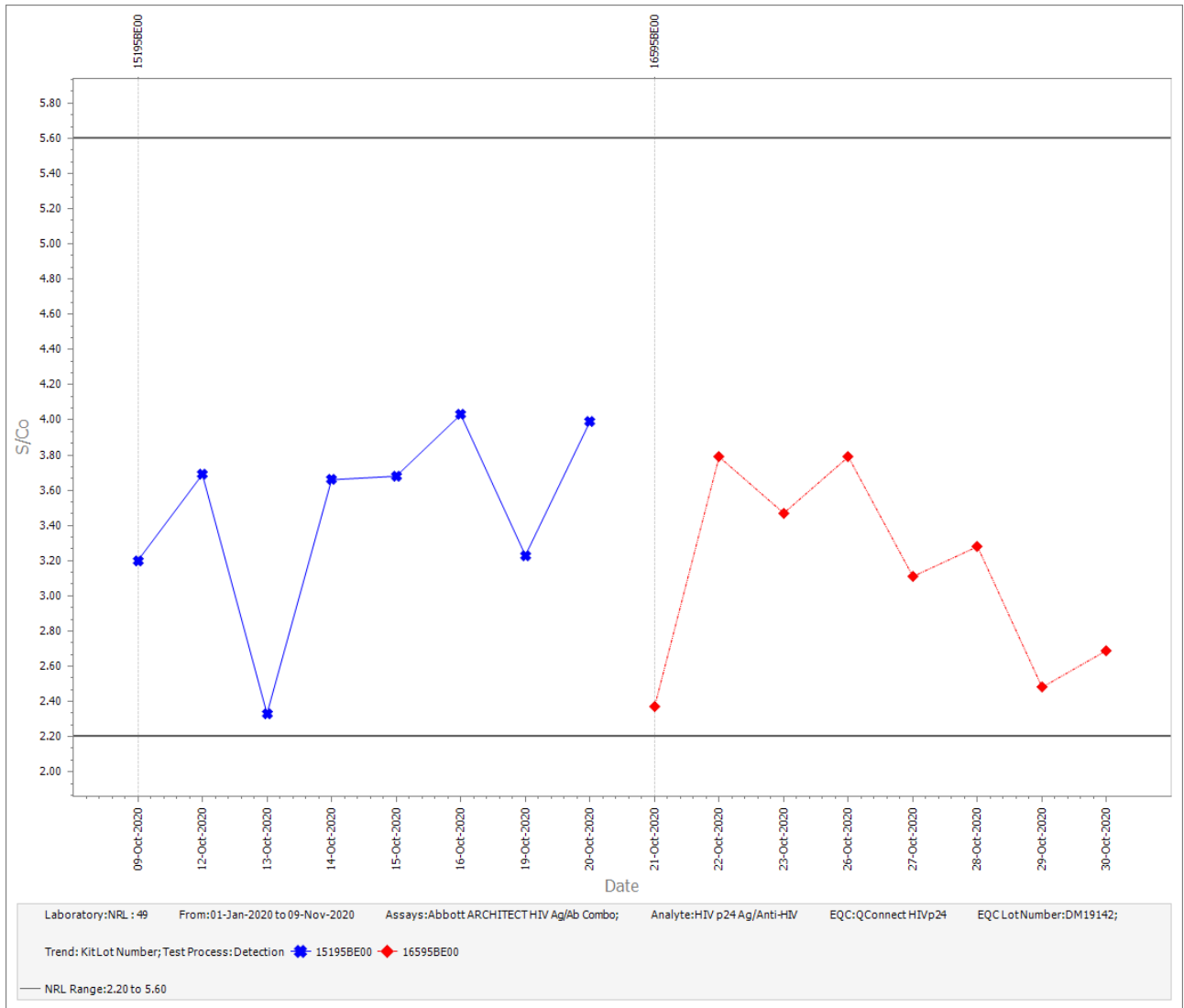


Figure 15: Participant 49 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

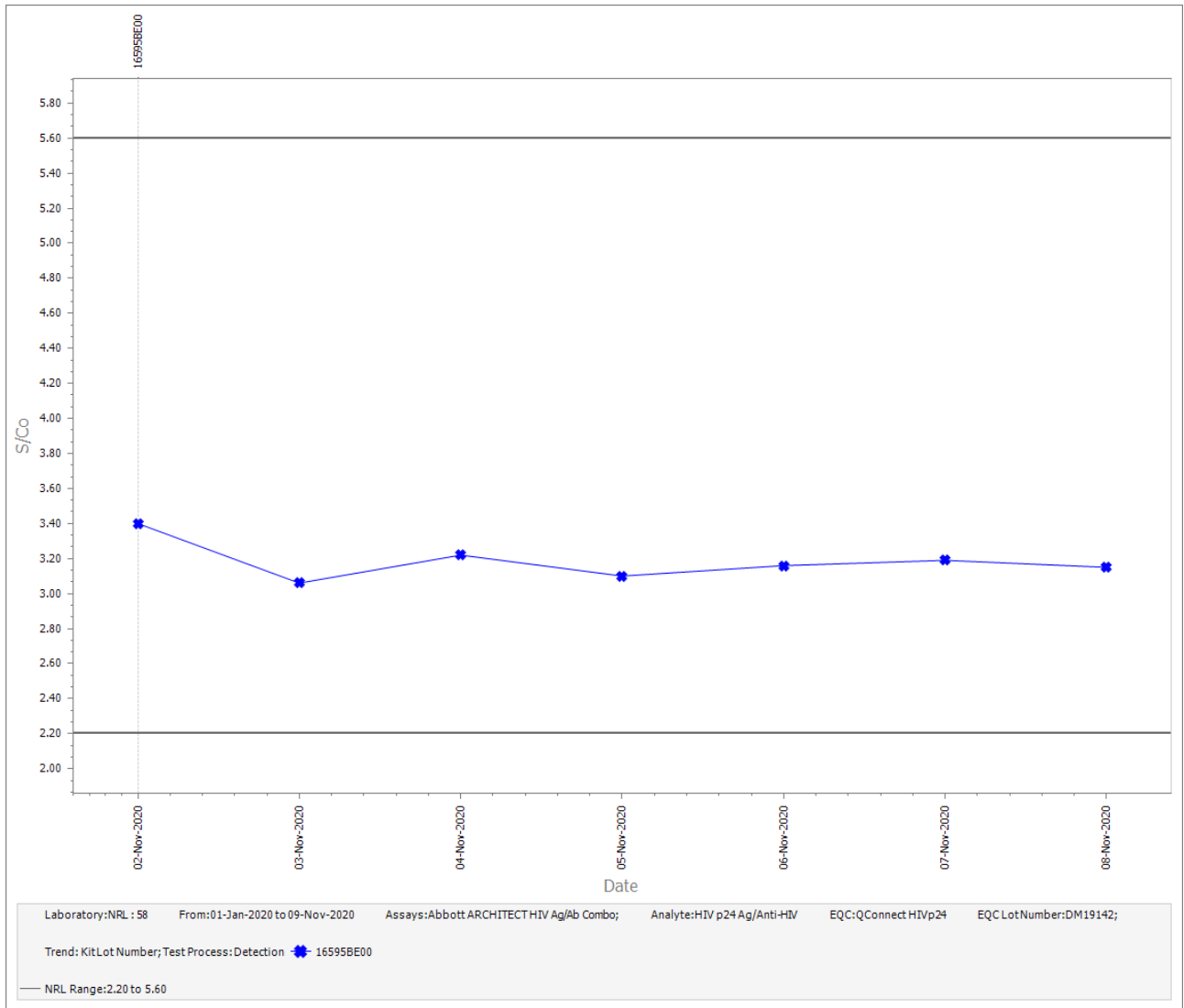


Figure 16: Participant 58 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

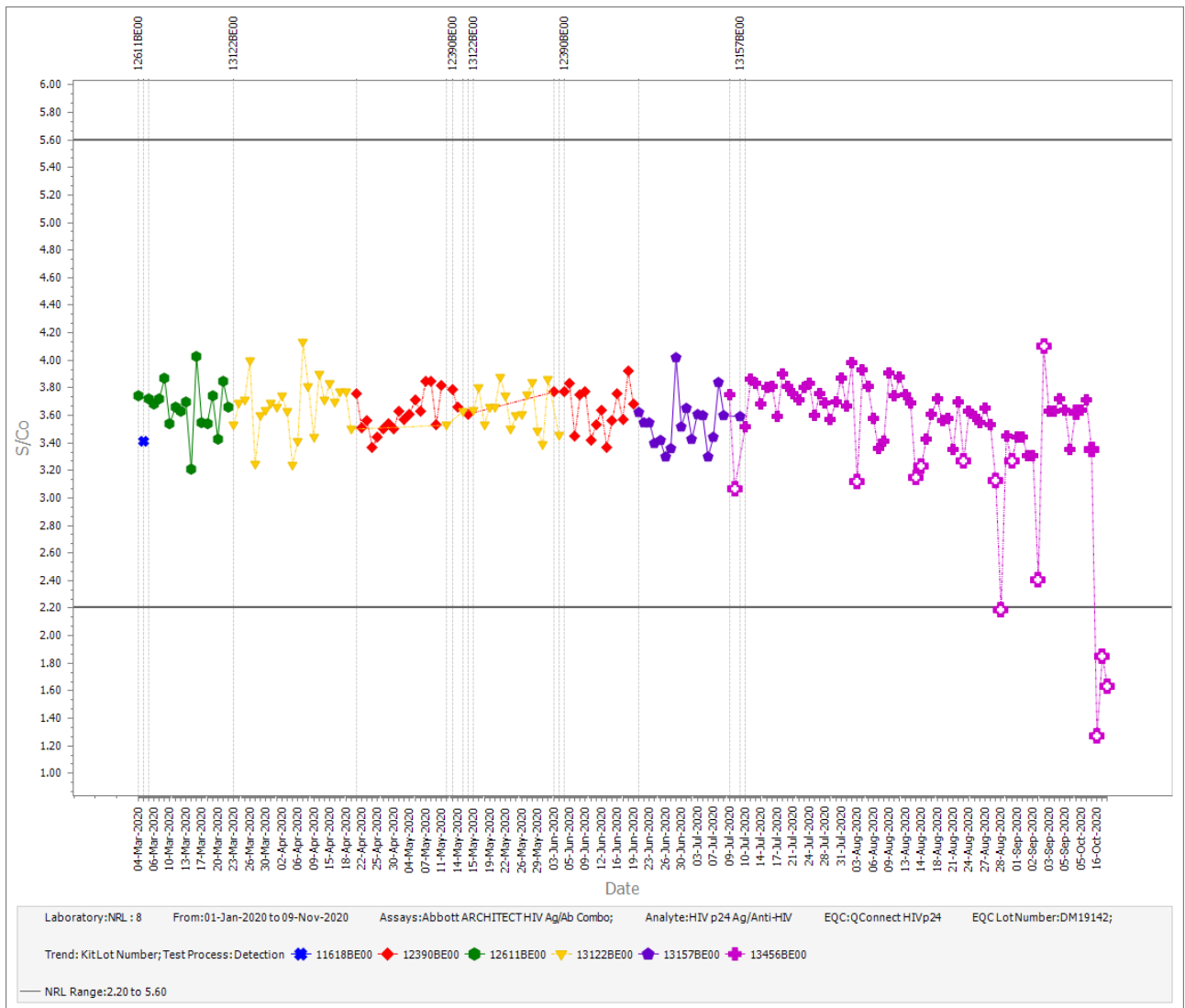


Figure 17: Participant 8 data for QConnect HIVp24, DM19142, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

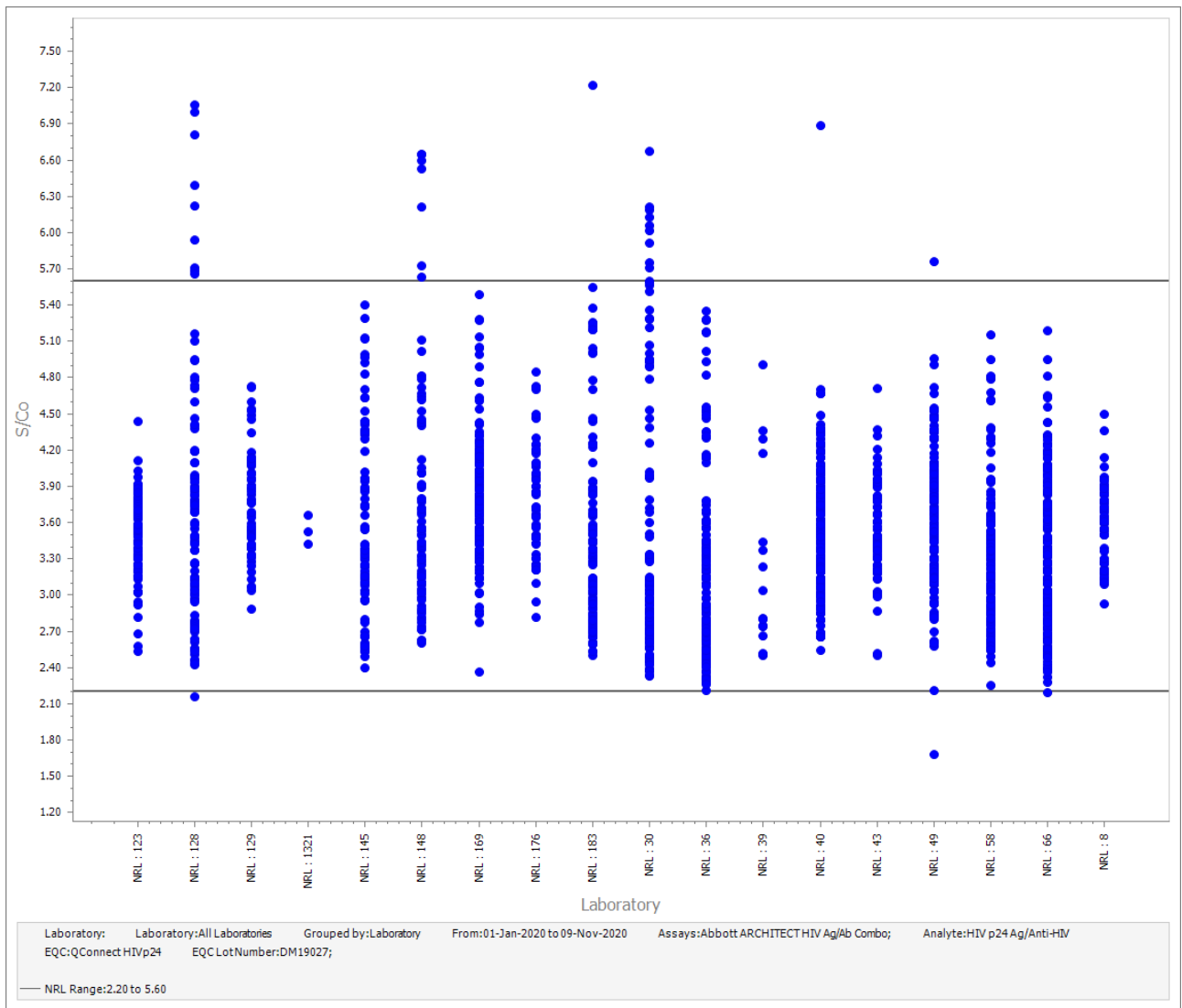


Figure 18: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by laboratory.



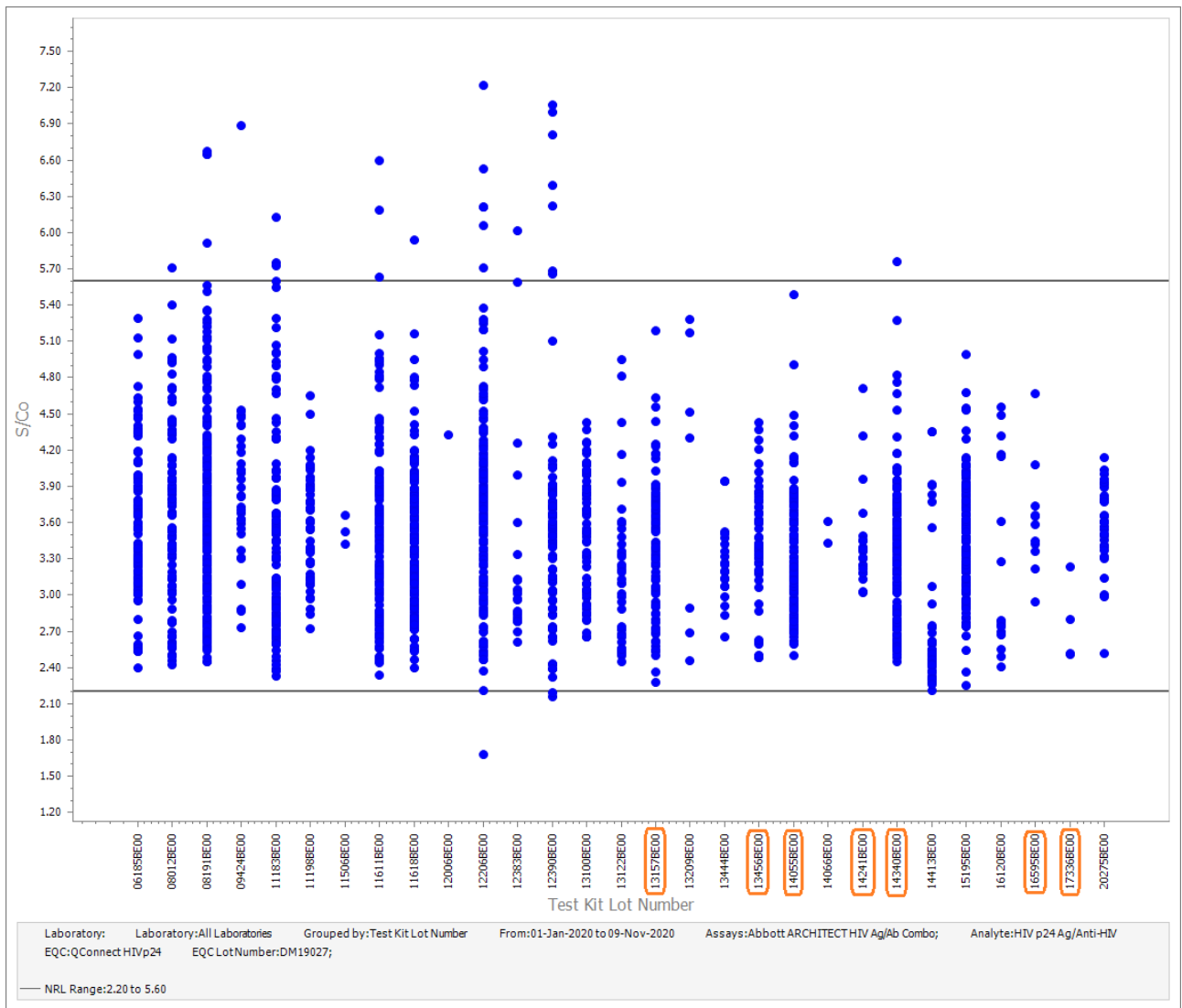


Figure 19: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

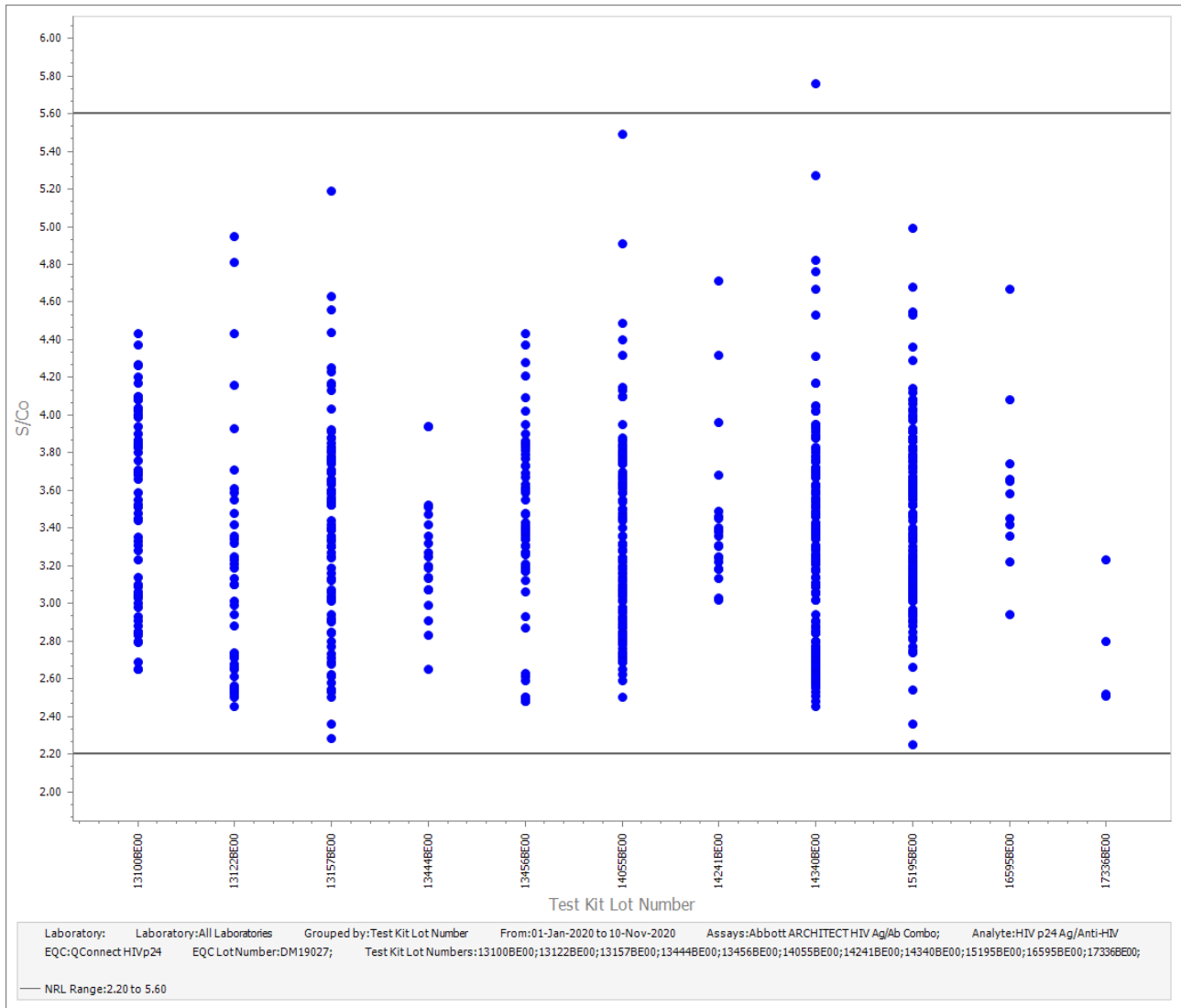


Figure 20: Peer group data for QConnect HIVp24, DM19027, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lots that are common with DM19142 usage.

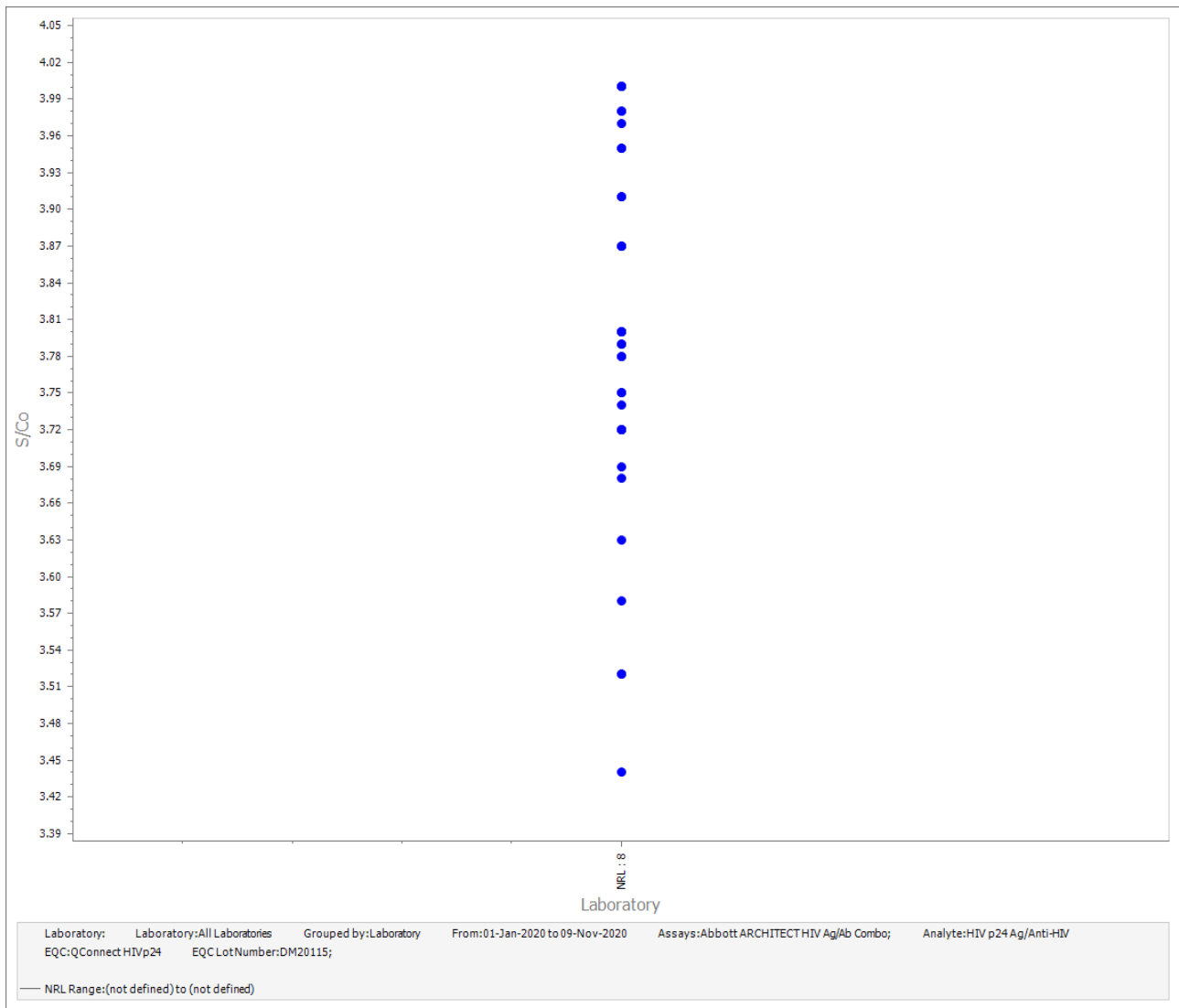


Figure 21: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by Laboratory.

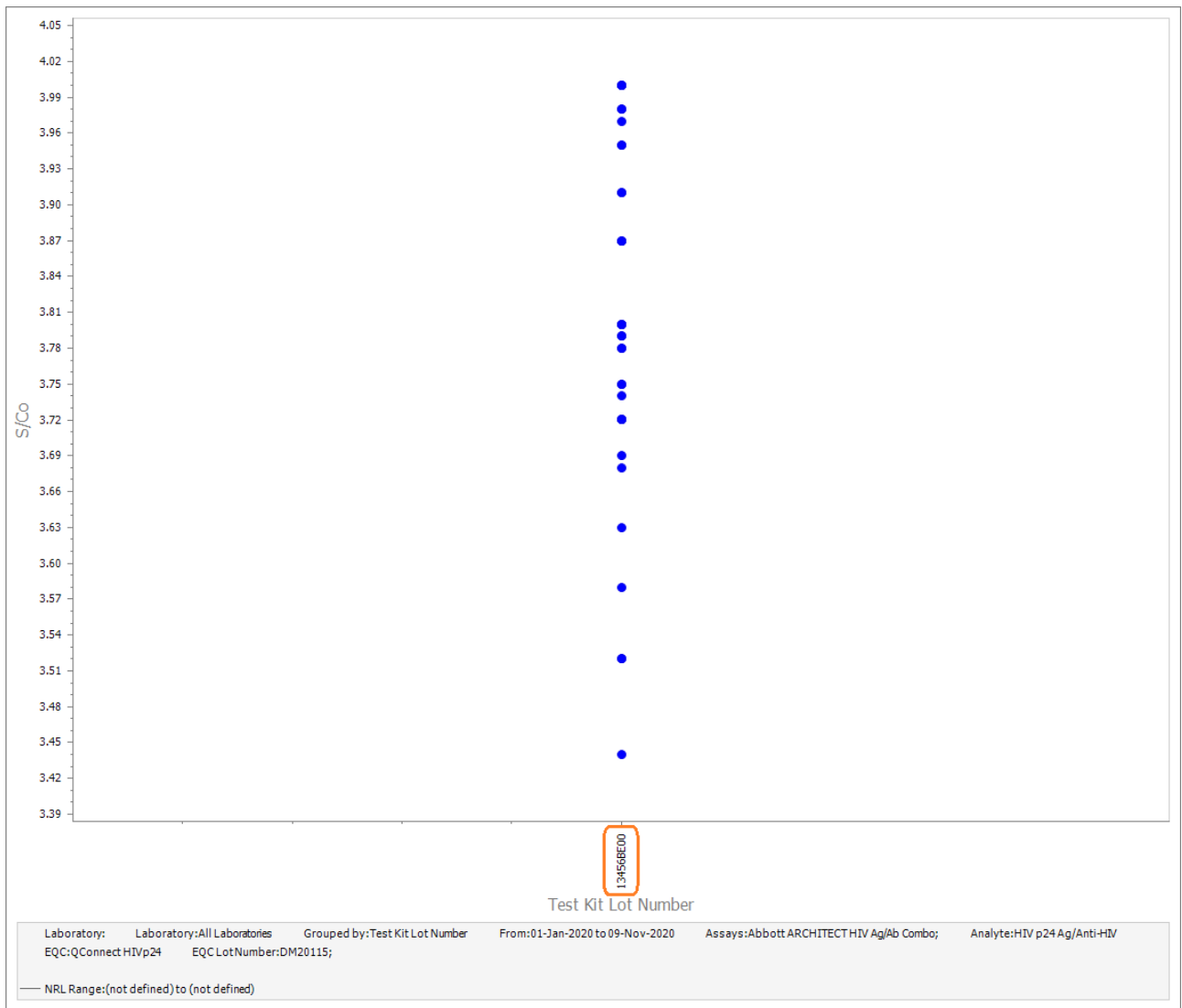


Figure 22: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lot.

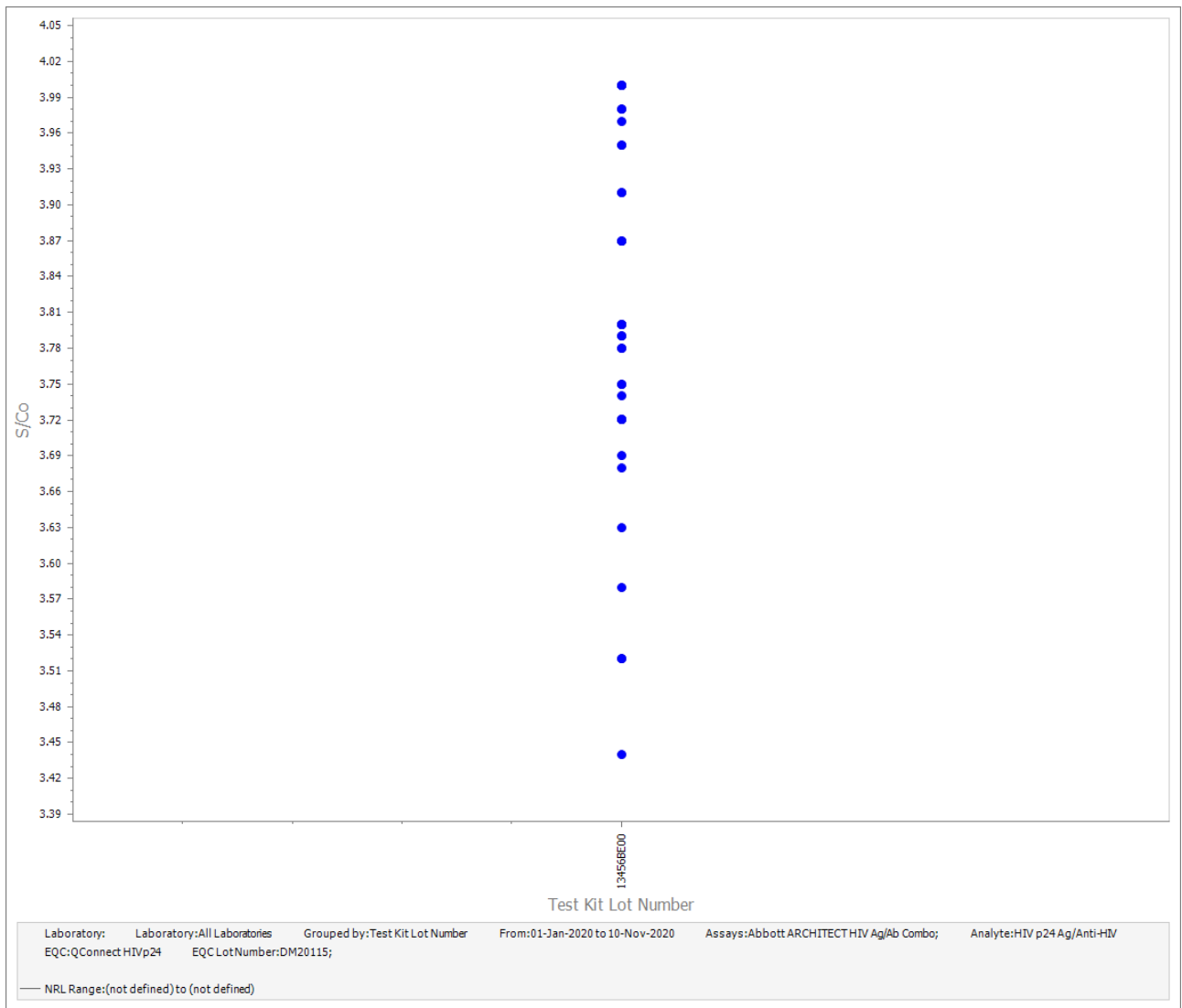


Figure 23: Peer group data for QConnect HIVp24, DM20115, for Abbott ARCHITECT HIV Ag/Ab Combo by reagent lots that are common with DM19142 usage.

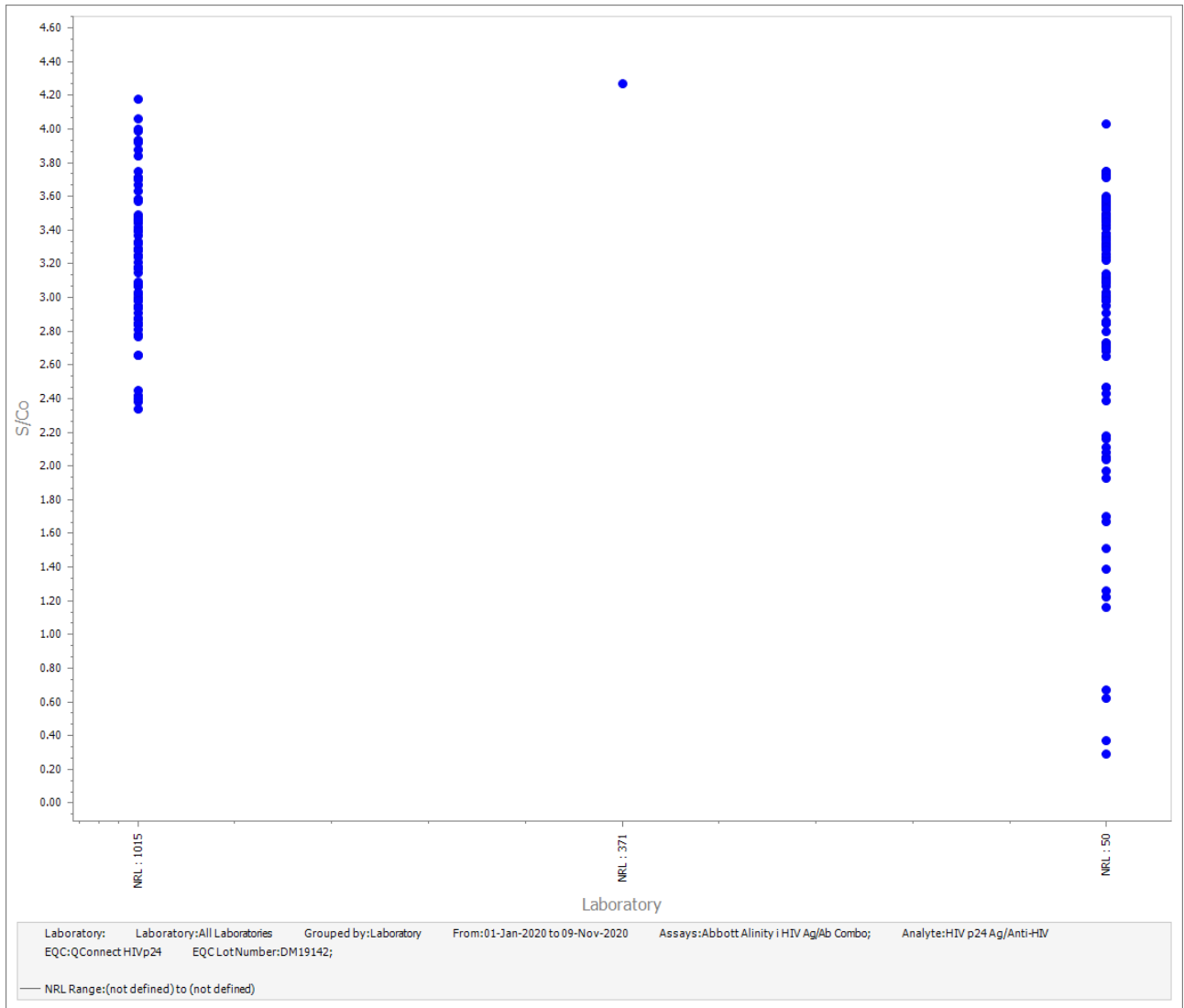


Figure 24: Peer Group data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by laboratory.

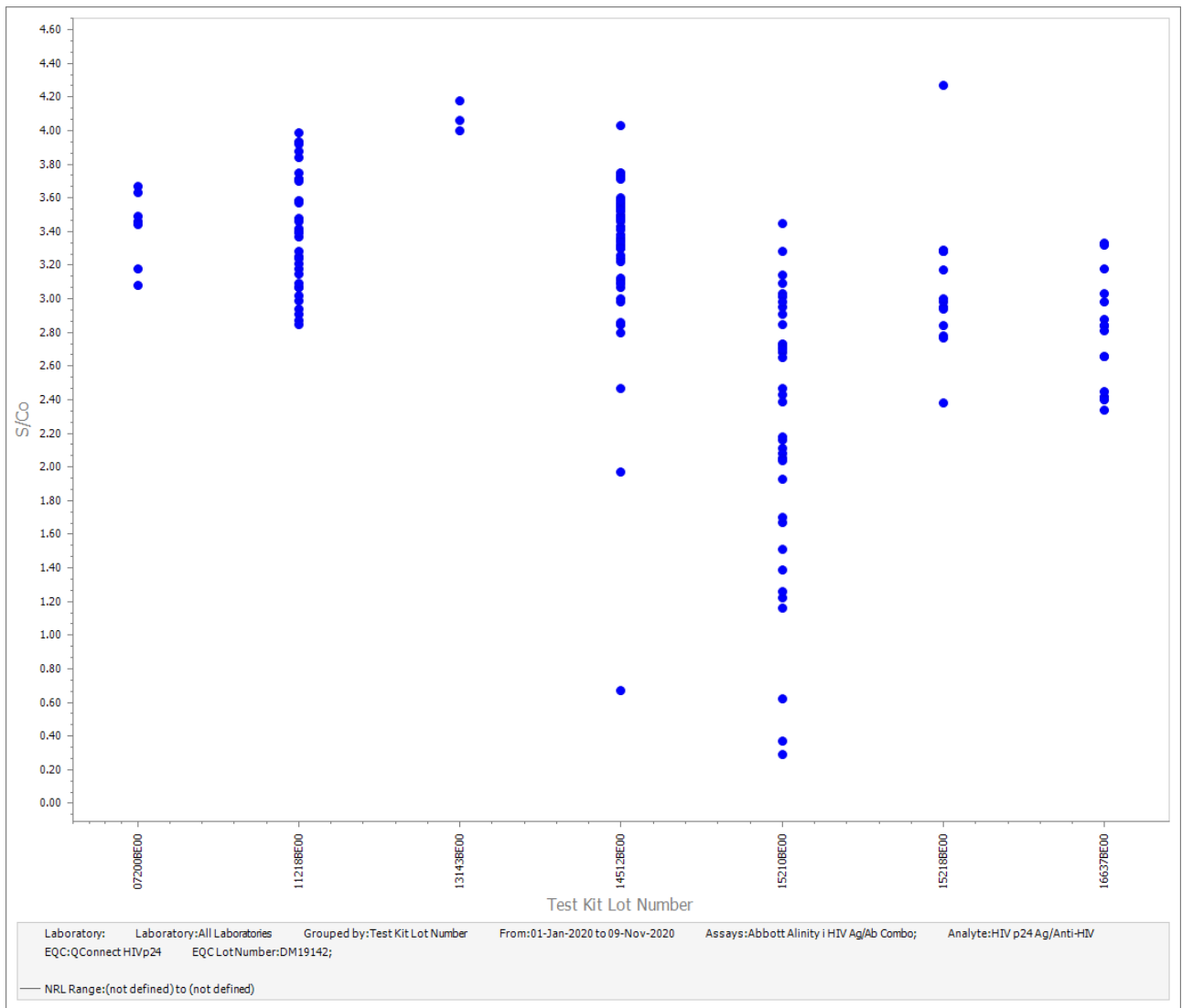


Figure 25: Peer Group data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

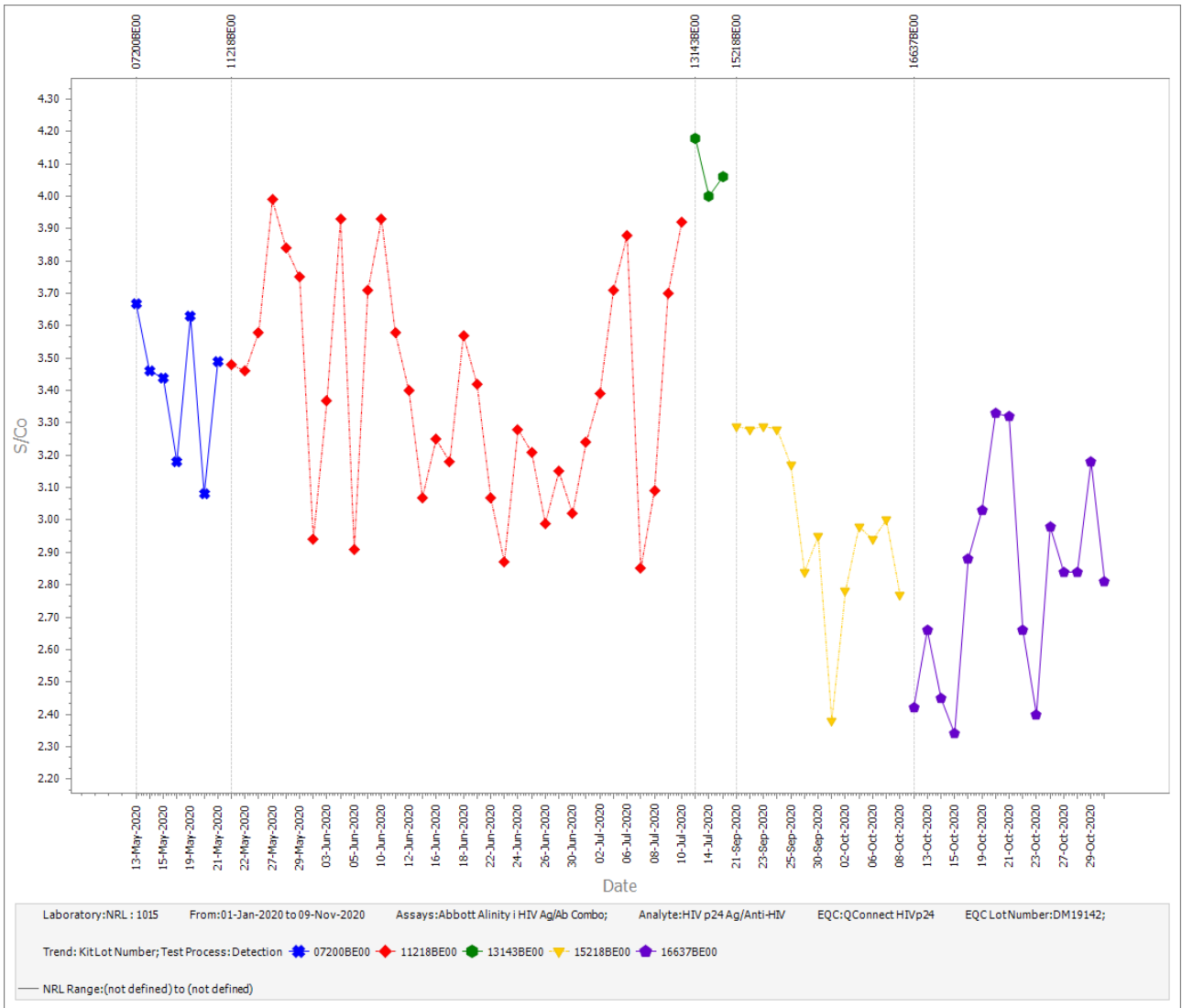


Figure 26: Participant 1015 data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.



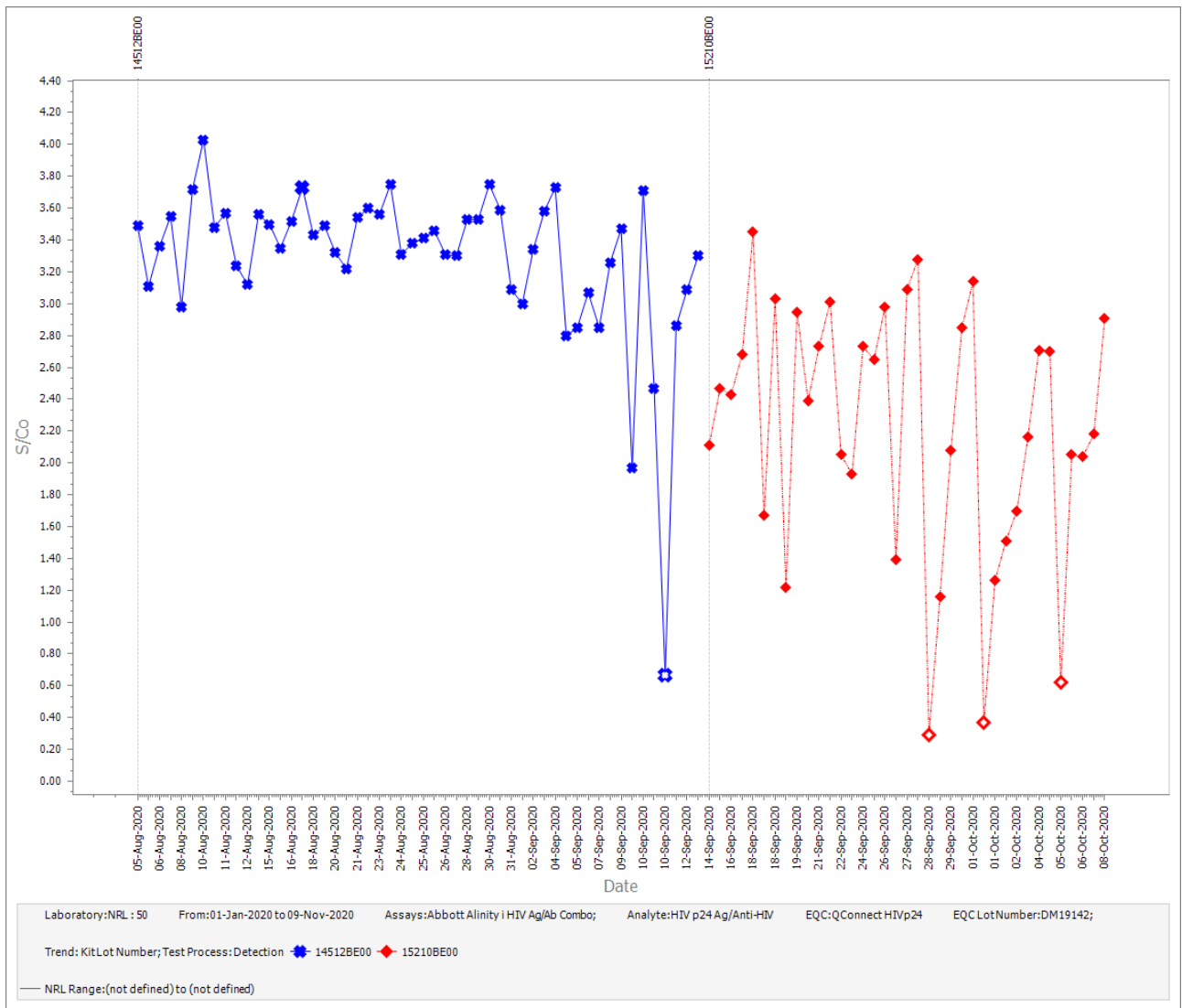


Figure 27: Participant 50 data for QConnect HIVp24, DM19142, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

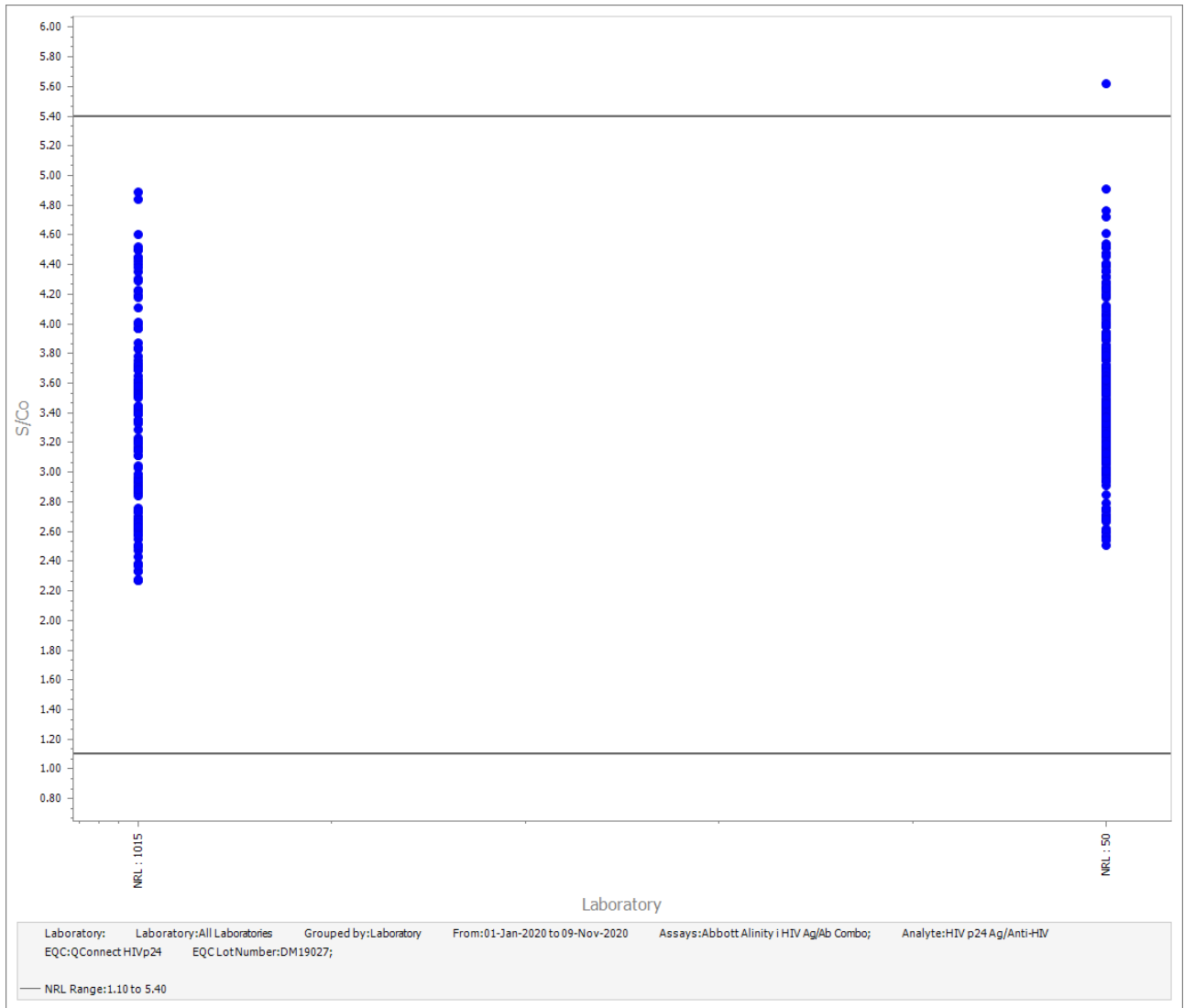


Figure 28: Peer Group data for QConnect HIVp24, DM19027, for Abbott Alinity i HIV Ag/Ab Combo by laboratory.

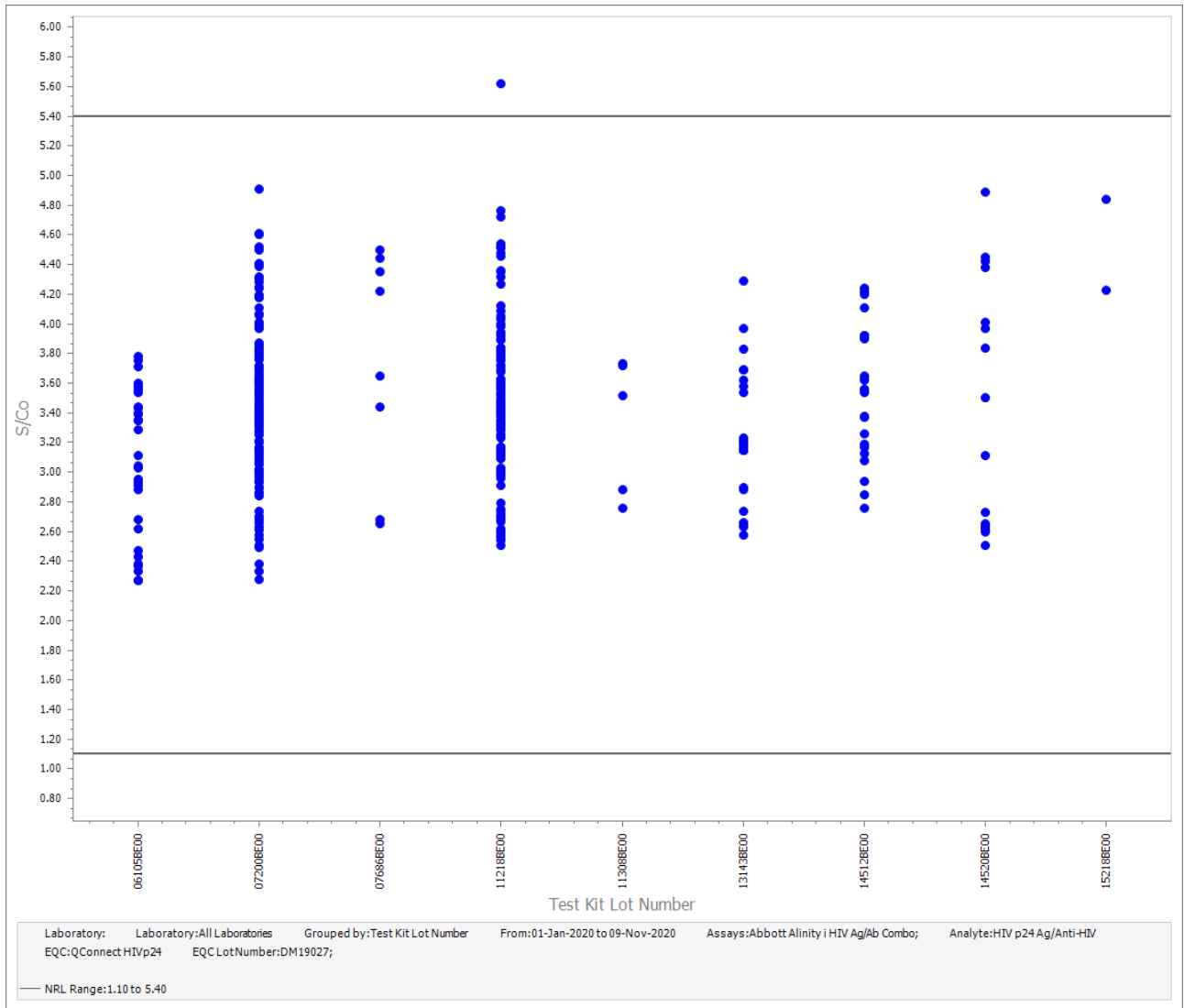


Figure 29: Peer Group data for QConnect HIVp24, DM19027, for Abbott Alinity i HIV Ag/Ab Combo by reagent lot.

Lab ID#	QC Lot Number	Order Date	Order sent to LFS	Packed at LFS	Shipped from LFS	Received at Lab.	Comments
NRL #8	DM19163	9/10/2020	9/10/20 estimate	13/10/2020	13/10/2020	14/10/2020	packed Friday, delivered Monday
	DM19163	24/08/2020	24/08/2020	24/08/2020	24/08/2020	27/08/2020	
	DM19163	20/07/2020	20/07/2020	21/07/2020	21/07/2020	22/07/2020	
	DM19163	28/05/2020	28/05/2020	29/05/2020	31/05/2020	3/06/2020	
	DM19163	4/03/2020	4/03/2020	5/03/2020	5/03/2020	6/03/2020	
	DM19163	30/01/2020	30/01/2020	30/01/2020	30/01/2020	31/01/2020	
	DM19163	5/08/2020	5/08/2020	5/08/2020	5/08/2020	7/08/2020	
	DM19163	17/03/2020	17/03/2020	17/03/2020	17/03/2020	18/03/2020	
NRL #12	DM19163	22/01/2020	22/01/2020	22/01/2020	22/01/2020	23/01/2020	
NRL #30	DM19163	5/08/2020	5/08/2020	6/08/2020	6/08/2020	7/08/2020	
	DM19163	25/05/2020	25/05/2020	26/05/2020	26/05/2020	27/05/2020	
	DM19163	4/03/2020	4/03/2020	4/03/2020	4/03/2020	5/03/2020	
NRL #36	DM19163	8/10/2020	8/10/20 estimate	9/10/2020	11/10/2020	12/10/2020	packed Friday, delivered Monday
	DM19163	4/02/2020	4/02/2020	4/02/2020	4/02/2020	5/02/2020	
NRL #49	DM19163	7/09/2020	7/09/2020	8/10/2020	8/10/2020	10/10/2020	
NRL #123	DM19163	11/09/2020	11/09/2020	11/09/2020	13/09/2020	14/09/2020	packed Friday, delivered Monday
	DM19163	10/03/2020	10/03/2020	11/03/2020	11/03/2020	12/03/2020	
NRL #128	DM19163	9/06/2020	9/06/2020	10/06/2020	10/06/2020	11/06/2020	
NRL #129	DM19163	20/07/2020	20/07/2020	21/07/2020	21/07/2020	22/07/2020	packed Friday, delivered Monday
	DM19163	31/01/2020	31/01/2020	31/01/2020	2/02/2020	3/02/2020	
NRL #145	DM19163	19/02/2020	19/02/2020	19/02/2020	19/02/2020	20/02/2020	
NRL #148	DM19163	10/07/2020	10/07/2020	12/07/2020	12/07/2020	14/07/2020	
	DM19163	10/03/2020	10/03/2020	11/03/2020	11/03/2020	13/03/2020	
NRL #176	DM19163	15/10/2020	15/10/20 estimate	16/10/2020	18/10/2020	19/10/2020	packed Friday, delivered Monday
	DM19163	19/03/2020	19/03/2020	19/03/2020	19/03/2020	20/03/2020	
NRL #183	DM19163	7/07/2020	7/07/2020	7/07/2020	7/07/2020	9/07/2020	
	DM19163	19/02/2020	19/02/2020	19/02/2020	19/02/2020	20/02/2020	

Table 1: Ordering and shipping information for QConnect HIVp24 DM19142, provided by NRL administration and LFS.

