



# QC SEROLOGY INVESTIGATION PMM-QC-606

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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 Marina Karakaltsas, 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](http://www.nrlquality.org.au)  
A.B.N. 52 004 705 640



## 1 Introduction

Daily QC data reviews showed that Participant 418 had results outside the NRL QConnect limits for QConnect Blue:DM16233 tested in the Abbott ARCHITECT rHTLV-I/II assay. Results reported by Participant 418 and other laboratories were reviewed.

## 2 Findings

*All charts are for data submitted to EDCNet between 01/01/2018 and 18/04/2018*

- Figure 1 – Scatter chart showing all data for all laboratories for QC lot DM16233
- Figure 2 – LJ chart for Laboratory 418 showing Blue data by reagent lot
- Figure 3 – LJ chart for Laboratory 8 showing Blue data by instrument
- Figure 4 – LJ chart for Laboratory 8 showing Kit Positive data by reagent lot
- Figure 5 – LJ chart for Laboratory 30 showing Blue data by instrument
- Figure 6 – LJ chart for Laboratory 8 showing Kit Positive data by instrument
- Figure 7 – LJ chart for Laboratory 43 showing Blue data by instrument
- Figure 8 – LJ chart for Laboratory 43 showing Kit Positive data by instrument
- Figure 9 – LJ chart for Laboratory 290 showing Blue data by instrument

## 3 Conclusion

Participant's 8, 30, 43, 290 and 418 all showed shifts in Blue data which were above the NRL's upper limit of 3.04 S/Co (Figures 2, 3, 5, 7 & 8).

Participants 8, 30 and 43 provided Kit Positive data which also showed shifts in reactivity which coincided with the shift in reactivity observed for the Blue (Figure 4, 6, & 8).

Participant 8's data showed shifts in Blue and Kit Positive data at about the same time (Figure 3 and 4).

Participant 30's data showed shifts in data for both their instruments but most data outside NRL's upper limit was for instrument ARCHITECT i1000SR (Figure 5)

The shift in Participant 43's data in January 2018 was mainly for their instrument ARCHITECT i2000SR (2) which coincided with their Kit Positive data (Figures 7 & 8).

It appears that these shifts in reactivity might be due to instrument calibration.

## 4 Recommendations

NRL recommends that all participants identify whether instrument calibration coincided with these shifts in reactivity or whether there was a change in a reagent used in the assay test process or if there is any other reason. It would also be interesting to know if all participants used the same calibration kit.

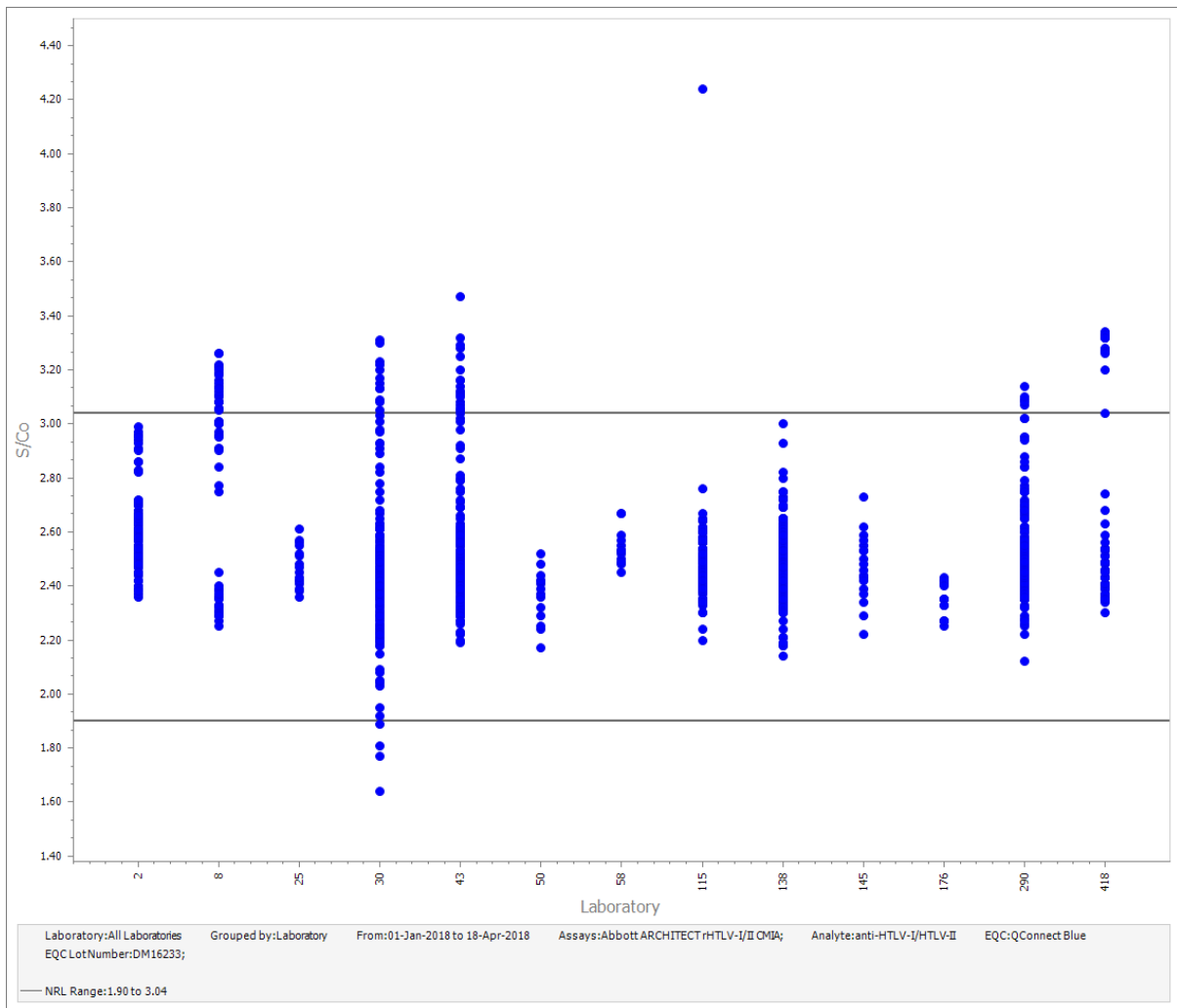


Figure 1

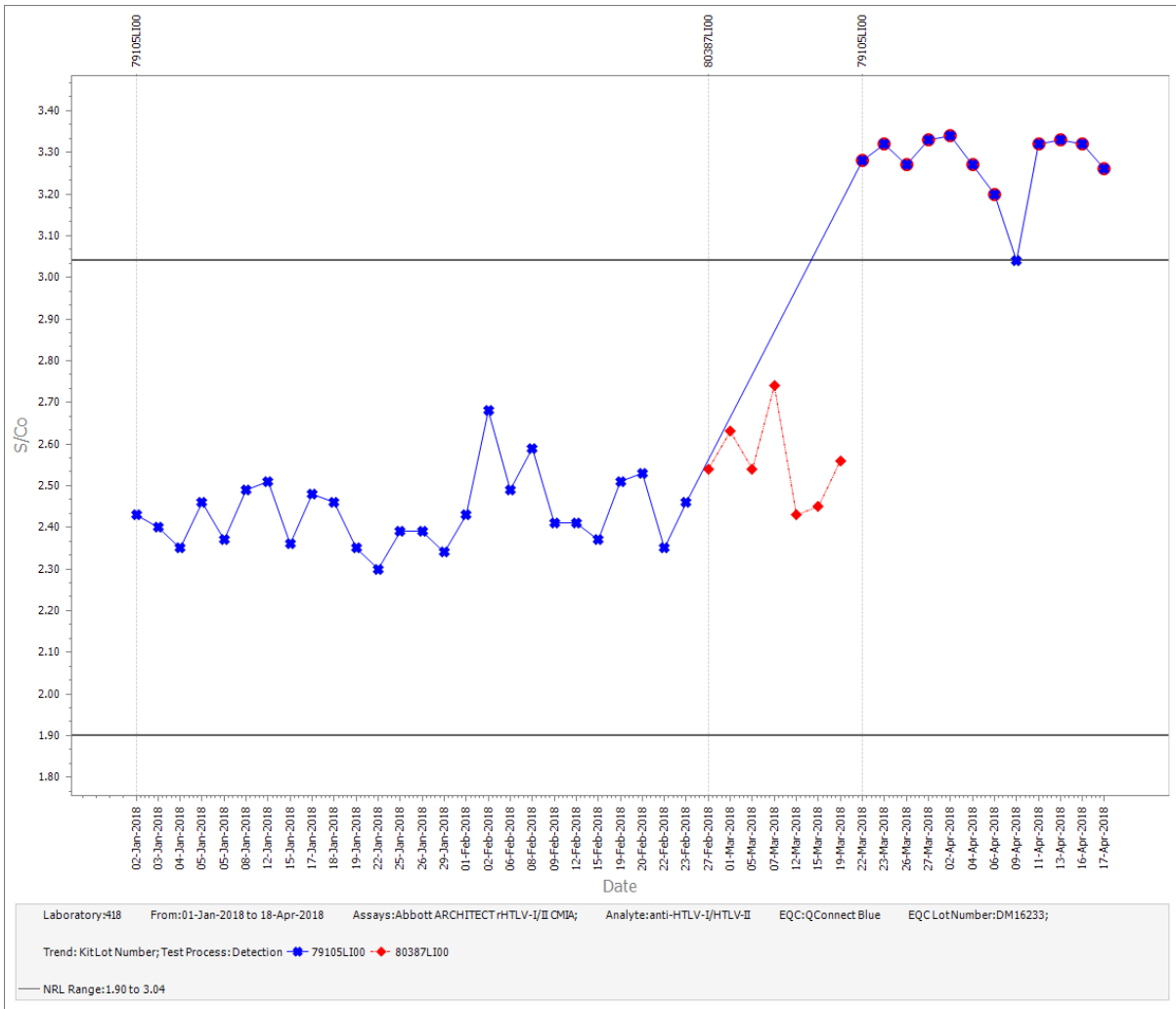


Figure 2

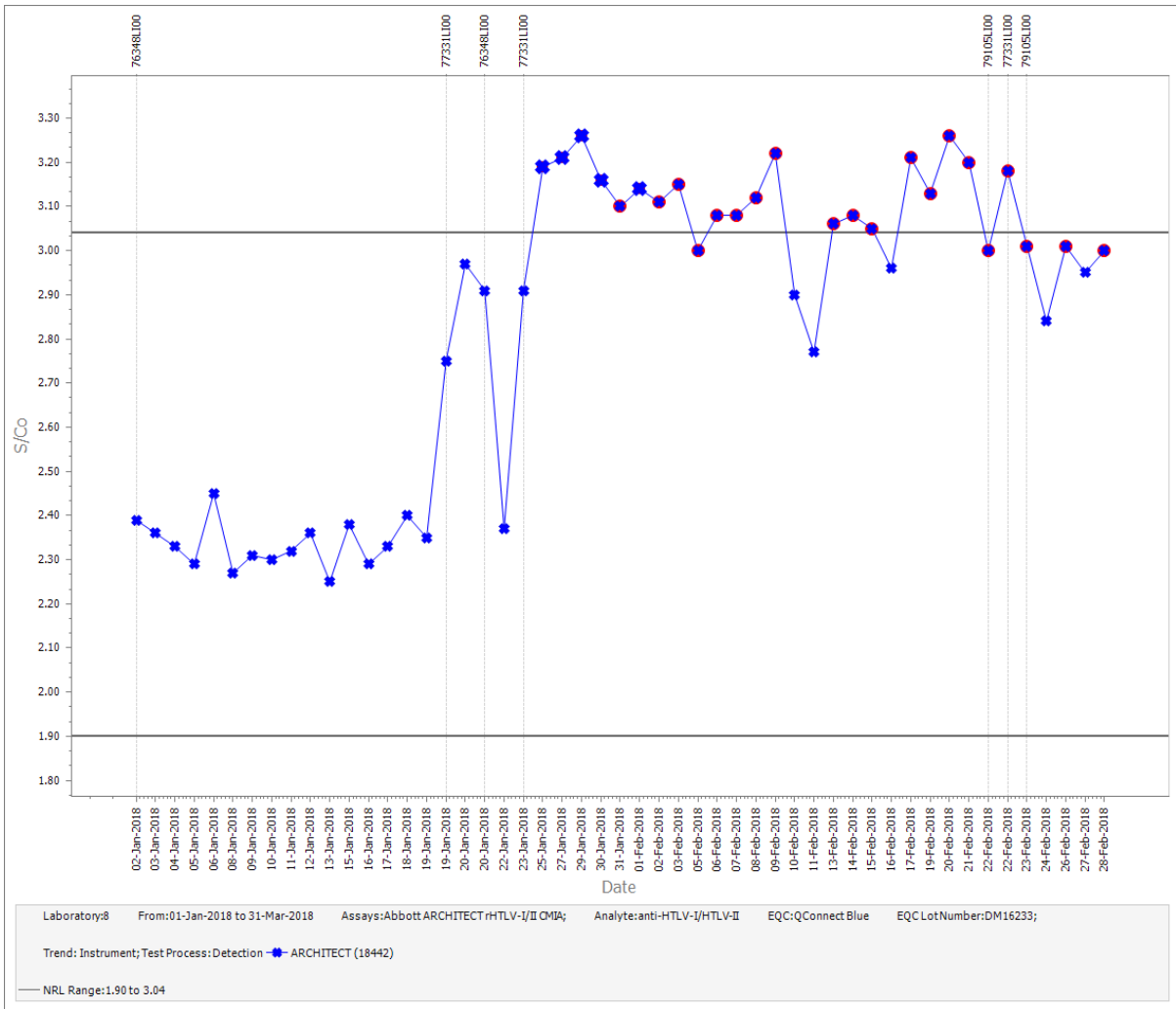


Figure 3

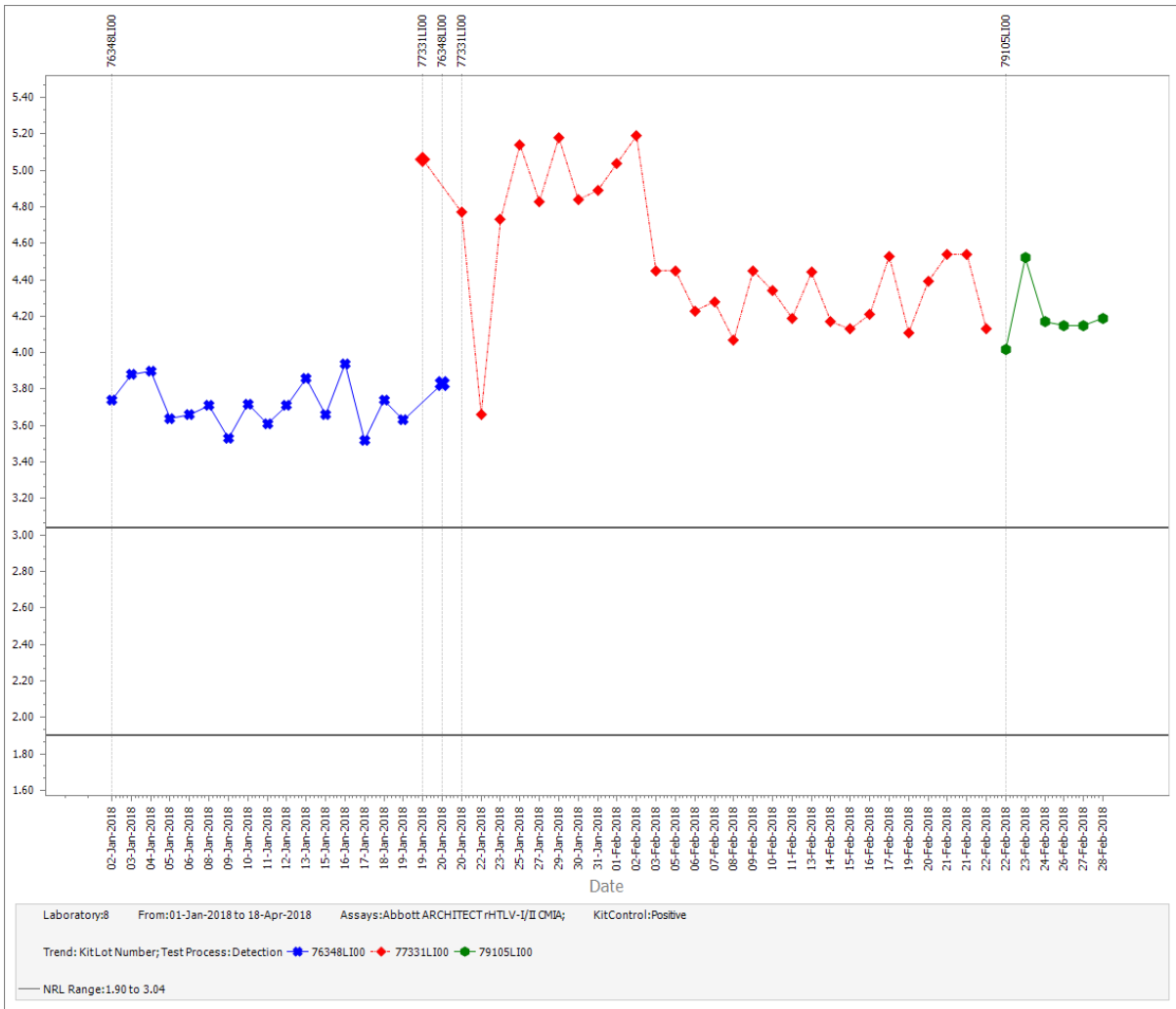


Figure 4

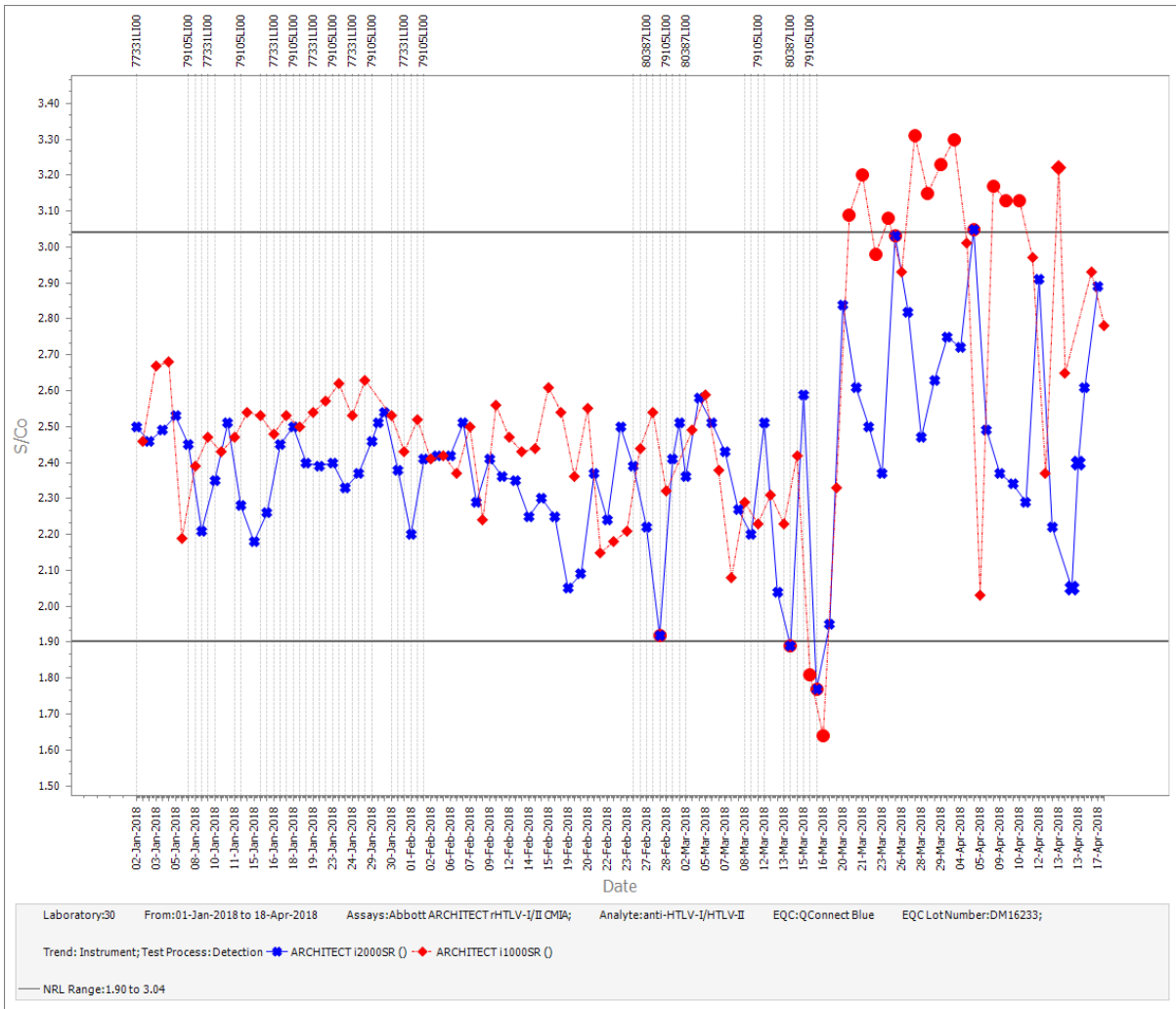


Figure 5



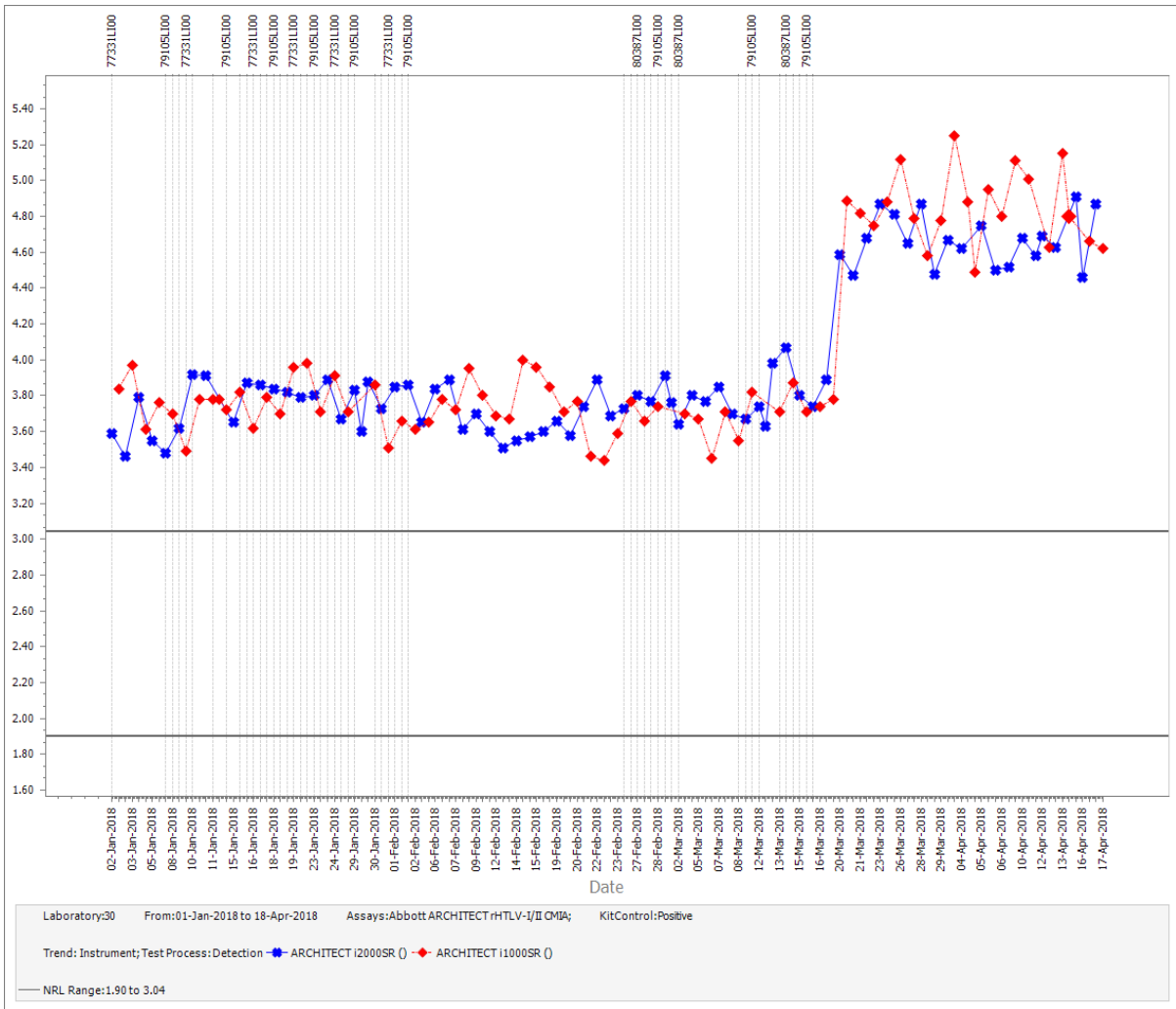


Figure 6

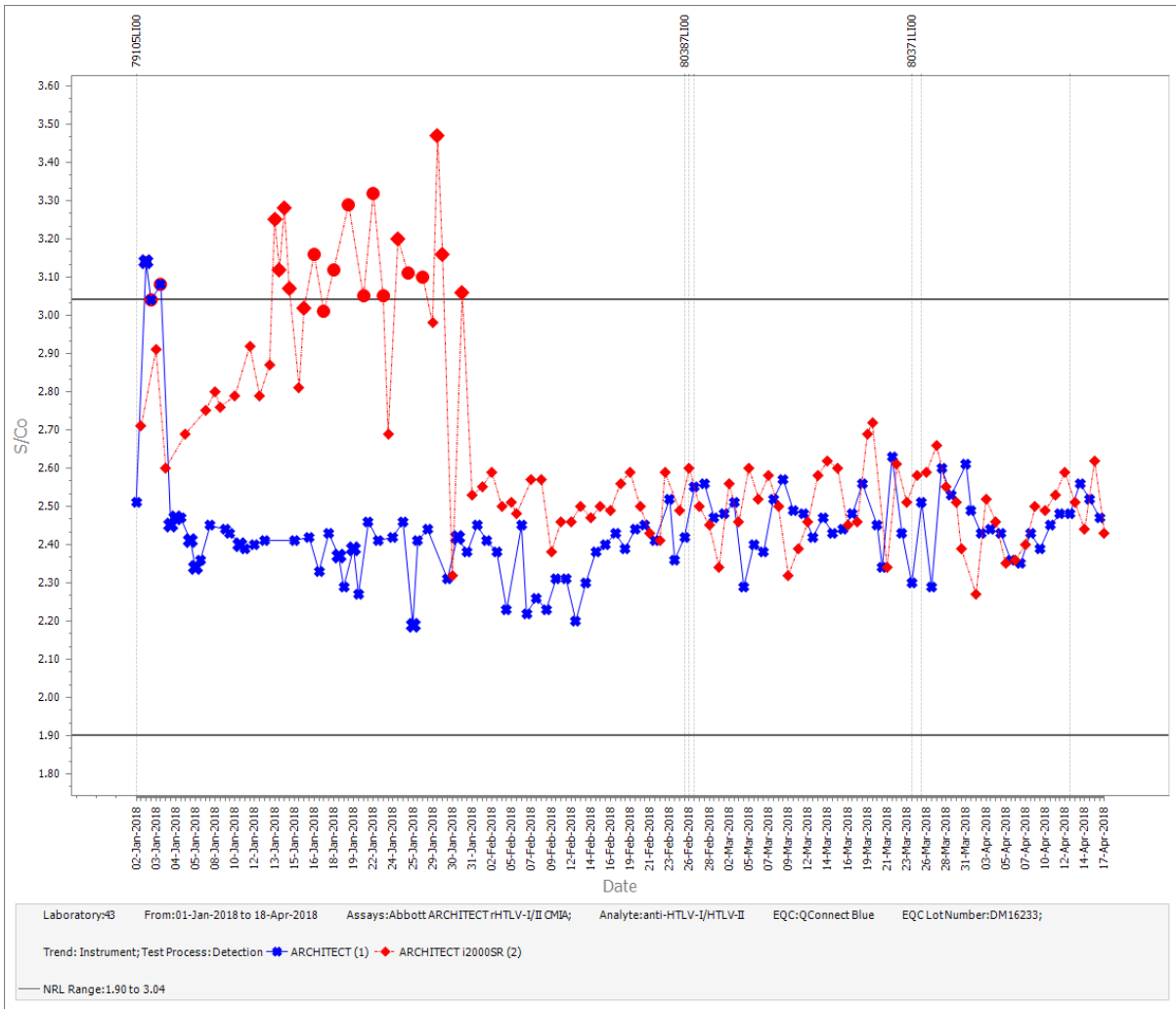


Figure 7

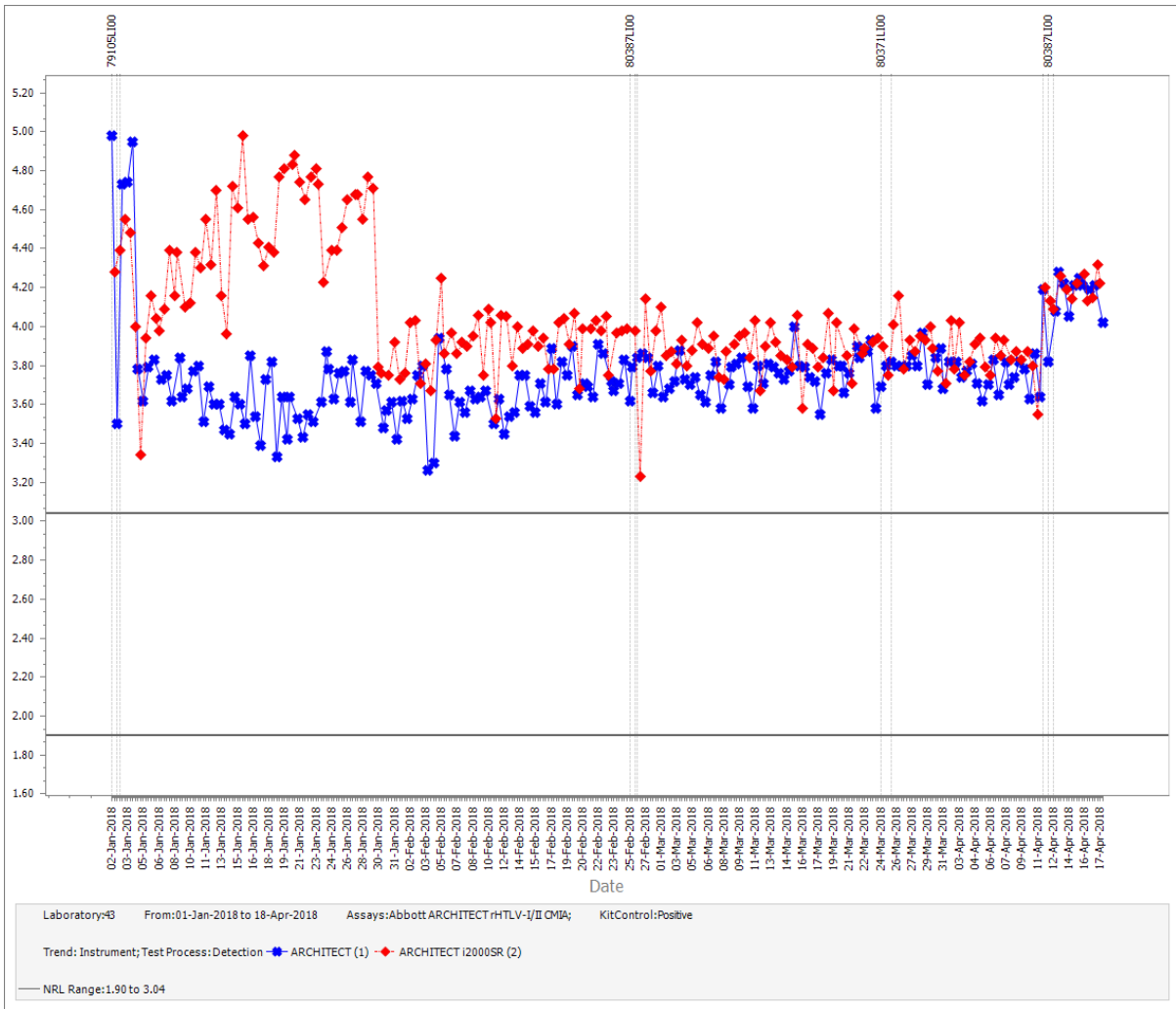


Figure 8

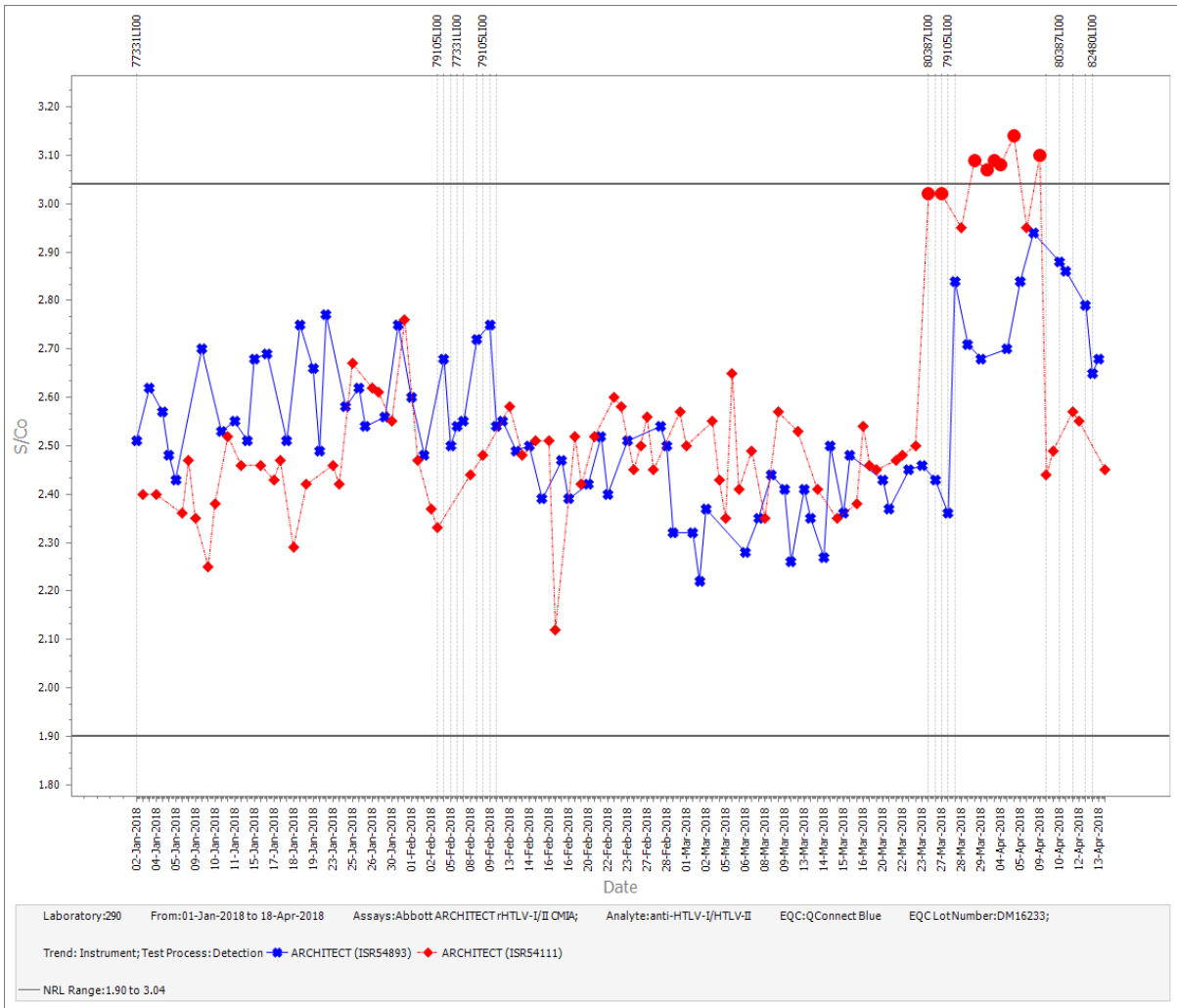


Figure 9