

QC INVESTIGATIONS

Investigation of the rise and fall in reactivity of QConnect Blue (413301) data submitted by Participant 877 for the Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) ChLIA



NRL is:

- Accredited for compliance with ISO 17043, with NATA Accreditation Number 14253;
- A World Health Organisation (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Bloodborne Infections.

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1 Introduction

During a routine data review of the QConnect EDCNet database, data submitted by Participant 877 for QConnect Blue (413301) when tested in the Siemens ADVIA Centaur HIV Ag/Ab Combo assay appeared to rise and fall frequently over time.

2 Findings

Data submitted by Participant 877 for QConnect Blue (413301), kit positive and negative control all presented with a rise and fall in reactivity over time (Figures1-3). This pattern of reactivity also appears when Participant 877 tests with QConnect Blue (402302) in the Siemens ADVIA Centaur HIV Ag/Ab Combo assay (Figure 4).

Data for QConnect Blue (413301) tested by Participant 877 in the assays; Siemens ADVIA Centaur HCV, Siemens ADVIA Centaur Anti-HBs2 and Siemens ADVIA Centaur HBsAgII did not show the same pattern of reactivity (Figures 5, 6 and 7).

3 Conclusion

Participant 877 informed the NRL that the highest result for QConnect Blue (413301) tested in the Siemens ADVIA Centaur HIV Ag/Ab Combo occurs when they calibrate the assay and then over a week or two the values drop until they recalibrate and the cycle begins again. NRL contacted the manufacturer to make a comment. The manufacturer asked for more information before making a statement.

4 Recommendations

NRL will recommend Participant 877 contact the assay manufacturer who will work with them to determine if there is a calibration problem with their assay.

NRL will investigate further with other participants' data to identify whether this phenomenon is occurring with other participants.

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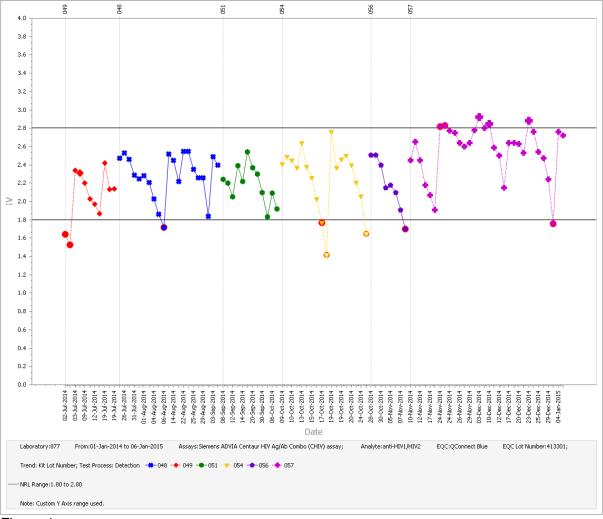


Figure 1

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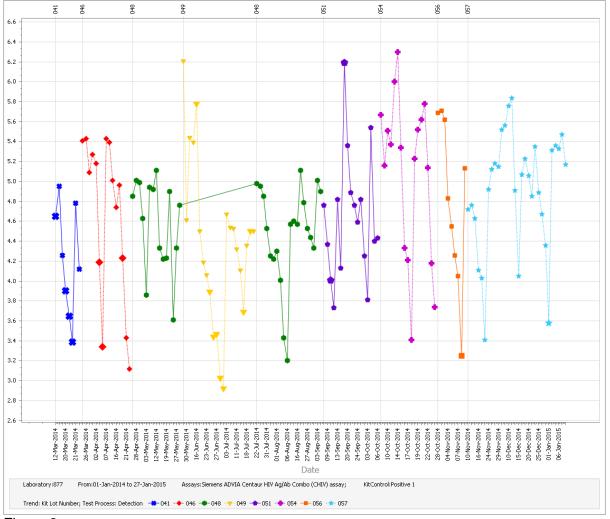


Figure 2

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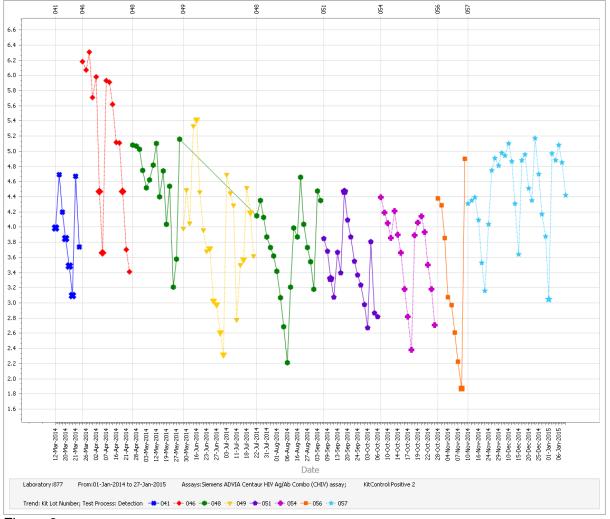


Figure 3

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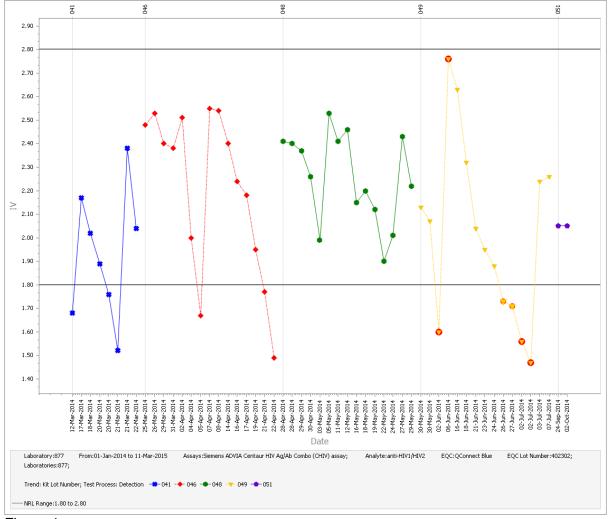


Figure 4

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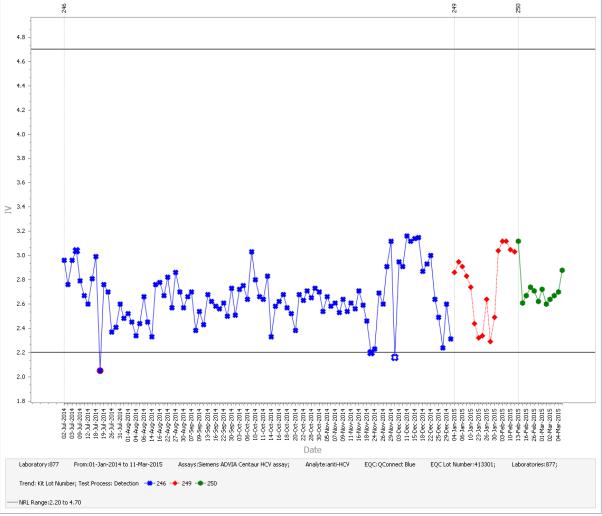


Figure 5

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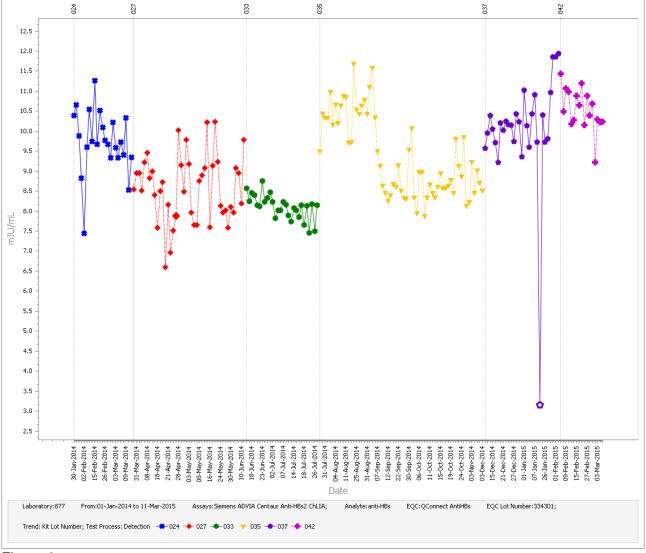


Figure 6

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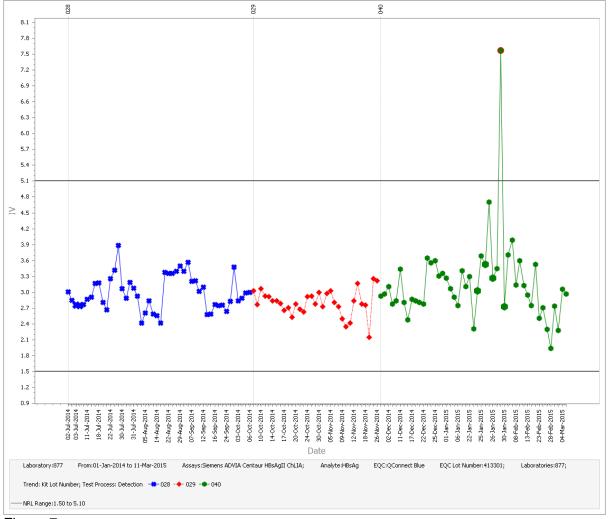


Figure 7

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Orders and Product Enquiries:



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