

# QC Services Investigation: PMM-QC-1593



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### CONTENTS

INTRODUCTION	3
FINDINGS	3
DISCUSSION	3
RECOMMENDATIONS	4

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## **INTRODUCTION**

During monthly review of EDCNet data, an increase in variation was observed for Optitrol Blue lots DM22009 and DM22121 on the Abbott Alinity s Anti-HTLV I/II assay. Feedback provided by DiaMex, confirmed new HTLV stock material was used in the manufacturing of Optitrol Blue lots DM22009 & DM21121.

This investigation reviewed data reported to EDCNet for Optitrol Blue lots DM22009 and DM22121 reported for the Abbott Alinity s Anti-HTLV I/II assay and the Abbott Alinity i, Abbott Architect and DiaSorin Liaison platforms to establish if this variation was observed across any other platform.

#### **FINDINGS**

Below are the full listing of charts included in the investigation:

- Figure 1 Participant 1 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.
- Figure 2 Participant 3 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187 and DM22009, by instrument.
- Figure 3 Participant 5 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.
- Figure 4 Participant 11 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.

## DISCUSSION

All participant data reported to EDCNet for assays testing Optitrol Blue DM22009 and DM22121 on the Abbott Alinity s platform were investigated to establish whether there was any evidence of trends or patterns across the peer group. All other peer groups reporting data for Optitrol Blue DM22009 and DM22121 were also investigated to establish if the increased variation was observed on other platforms.

Figures 1 – 4 show data from Participants 1, 3, 5 and 11 for Optitrol Blue DM22187, DM22009 and DM22121 when tested on the Abbott Alinity s Anti-HTLV I/II assay. An increase in variation was observed for all four Participants when testing with Optitrol Blue DM22009, compared to data obtained on the previous Optitrol Blue lot in use, DM21187. Several reagent lots (RL), including 41573BE00, 43337BE00 and 44094BE00, were used across all Participants and for multiple Optitrol Blue lot numbers. A large increase in variation was observed for RL 41573BE00 for Participants 3 and 5, and for RL 44094BE00 for Participants 1 and 11, when comparing the performance of Optitrol Blue DM21187 to DM22009. This suggests the increase in variation was not caused by reagent lot variation. A shift up in S/Co and a decrease in unexpected variation was observed with the introduction of Optitrol Blue DM22121.

Data was reviewed on EDCNet for Participants 1, 3, 5 and 11 testing with Optitrol Blue DM22187, DM22009 and DM22121 on the Abbott Alinity s Anti-HCV, Abbott Alinity s HIV Ag/Ab Combo and Abbott Alinity s Syphilis assays. No significant changes were observed across the peer group for these assays.

Participant data reported for Optitrol Blue DM22009 and DM22121 on the Abbott Alinity i rHTLV-I/II I and Abbott ARCHITECT rHTLV-I/II assays were reviewed to establish if the variation noted on the Abbott Alinity s was observed on any other platforms. The increased variation observed for Optitrol Blue lots DM22009 and DM22121 on Abbott Alinity s Anti-HTLV I/II assay were not observed to the same degree for the Abbott Alinity i and Abbott ARCHITECT platforms.

## RECOMMENDATIONS

NRL contacted DiaMex to discuss the increased variation on the Abbott Alinity s Anti-HTLV I/II assay observed for Optitrol Blue lots DM22009 and DM22121 that had been manufactured with new HTLV stock material. Increased variation was consistent across the usage of Optitrol Blue lots DM22009 and DM22121 for the Abbott Alinity s Anti-HTLV I/II assay.

NRL recommended and DiaMex agreed to manufacture subsequent lots of Optitrol Blue at an adjusted concentration aimed to replicate data reported for lots prior to the introduction of the new HTLV stock material. Data for new lots of Optitrol Blue (manufactured at the new concentration), DM23017 onwards show little / no unexpected variation, with data consistent and within QConnect Ranges for all data reported to EDCNet.



Figure 1 – Participant 1 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.



Figure 2 – Participant 3 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187 and DM22009, by instrument.



Figure 3 – Participant 5 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.



Figure 4 – Participant 11 data for Abbott Alinity s Anti-HTLV I/II assay, Optitrol Blue DM21187, DM22009, and DM22121, by instrument.