

QC SERVICES INVESTIGATION PMM-QC-1784

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INTRODUCTION

During routine data reviews of EDCNet, NRL noted a downward trend between reagent lots for Participant 1866 on their Roche Elecsys Toxo IgM testing with Optitrol ToRCH M DM22191.

FINDINGS

- **Figure 1** – Participant 1866 data demonstrating reagent lot trend observed for Optitrol ToRCHM DM22191 when testing with Roche Elecsys Toxo IgM by reagent lot.
- **Figure 2** – Participant 1866 data demonstrating reagent lot trend observed for Optitrol ToRCHM DM22191 when testing with Roche Elecsys Toxo IgM by instrument.
- **Figure 3** – Roche PreciControl Toxo IgM lot number 716187 target sheet for Elecsys Toxo IgM reagent lot numbers 712936, 740657 and 783351 when tested on the cobas e 801 analyser.
- **Figure 4** – Roche PreciControl Toxo IgM lot number 774051 target sheet for Elecsys Toxo IgM reagent lot numbers 740657, 783351 and 799708 when tested on the cobas e 801 analyser.

DISCUSSION

Figures 1 and 2 show data for Participant 1866 reported on the Roche Elecsys Toxo IgM assay when testing with Optitrol ToRCH M DM22191. A steady downward trend was observed for both Roche cobas e 801 instruments between three reagent lots 712936, 740657 and 783351, with some data reported below QConnect Limits. Participant 1866 was the only participant reporting data for Roche Elecsys Toxo IgM to EDCNet.

Data were reviewed for Optitrol ToRCH M DM22191 for data reported to EDCNet for all other assays and platforms Optitrol ToRCH M is validated for with no similar trend or pattern observed.

NRL contacted Roche Diagnostics Australia for information regarding any change in the manufacturer or production of the affected reagent lots which could have contributed to the observed downward trend. Figures 3 and 4 are target value sheets provided by Roche for the Roche PreciControl Toxo IgM control kit. The data for PreciControl Toxo IgM level 2 control shows a similar pattern and lower values as was observed for Optitrol ToRCHM DM22191. Approximately a 10% drop of target values from reagent lots 712936 to 740657 and approximately a 5% from lot 740657 to 783351 were noted.

CONCLUSIONS

The target value sheets provided by Roche Diagnostics confirmed reagent lot variation.

RECOMMENDATIONS

NRL to review and adjust QConnect Limits for the Roche Elecsys Toxo IgM assay to reflect the reagent lot shift.

NRL will monitor the performance of future Roche Elecsys Toxo IgM reagent lots for shifts.

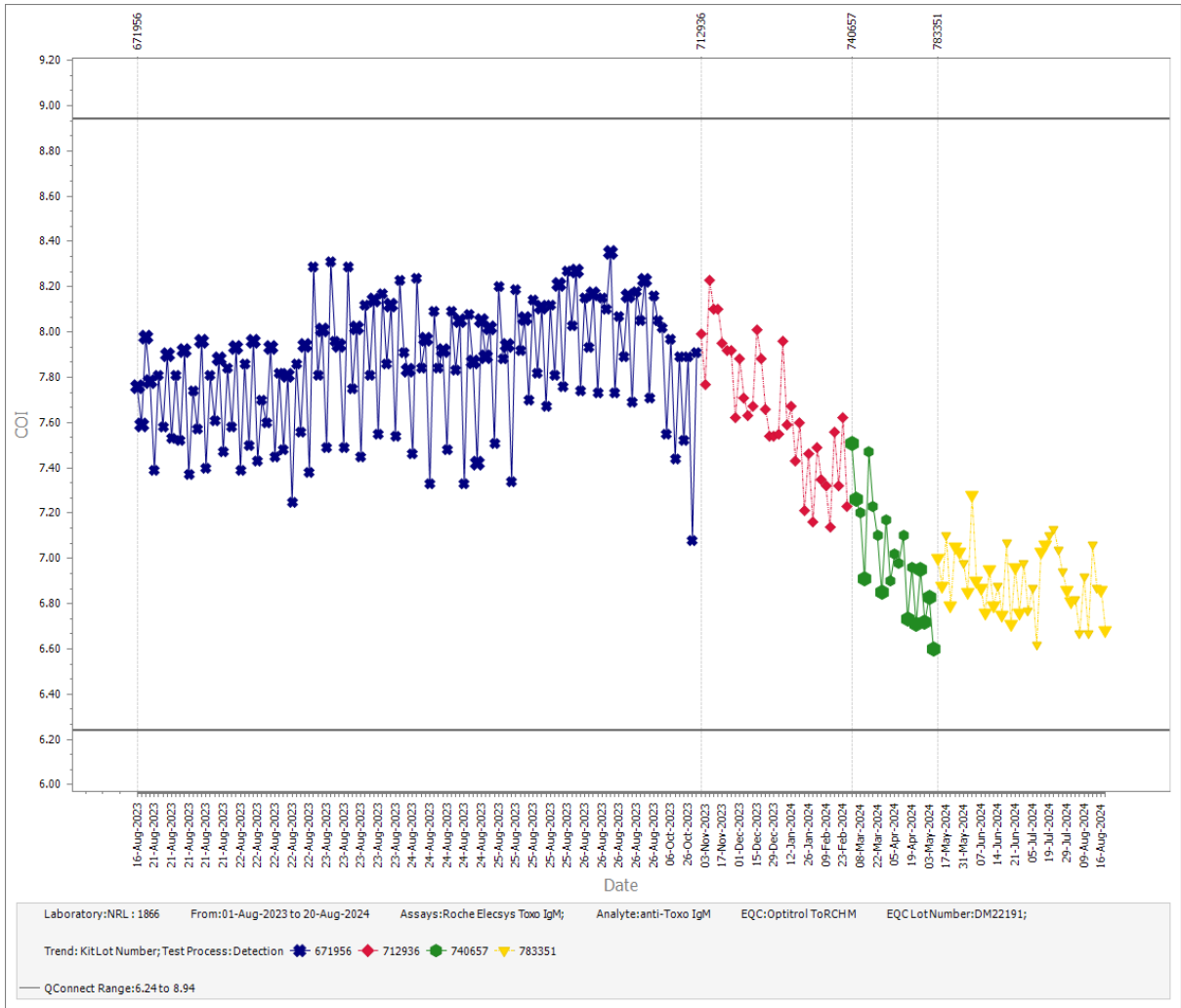


Figure 1 – Participant 1866 data demonstrating reagent lot trend observed for Optitrol ToRCH M DM22191 when testing with Roche Elecsys Toxo IgM by reagent lot.

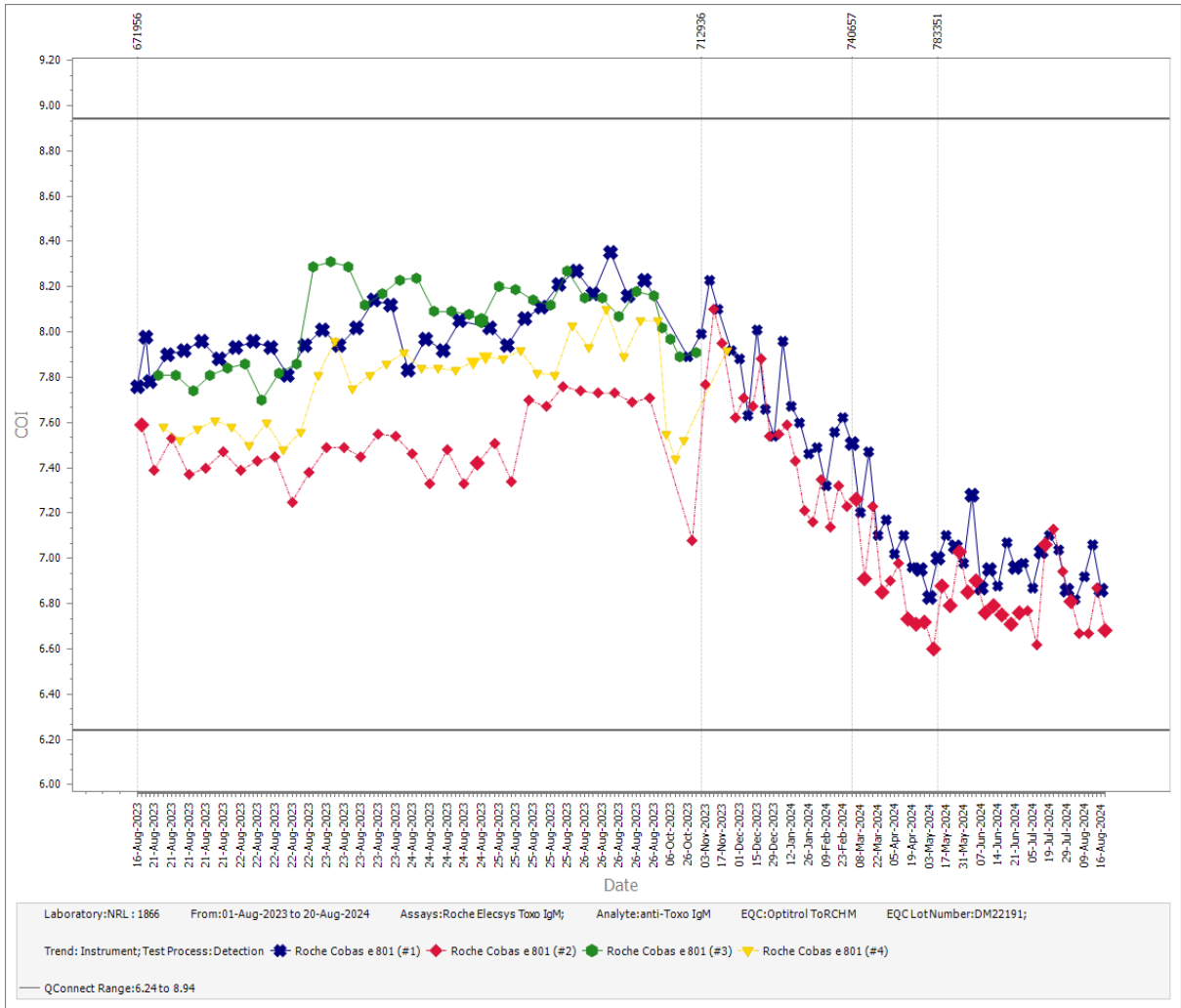


Figure 2 – Participant 1866 data demonstrating reagent lot trend observed for Optitrol ToRCH M DM22191 when testing with Roche Elecsys Toxo IgM by instrument.

V504618866190_699537a801v3

PreciControl Toxo IgM



REF 04618866190

LOT 716187 Ver.3

🕒 2024-03

cobas e 801 analyzer

Value sheet

Component	Method	[LOT]	PreciControl Toxo IgM level 1 [LOT] 699537			PreciControl Toxo IgM level 2 [LOT] 699538			Unit
			Value	Range	1SD	Value	Range	1SD	
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	712936	0.180	0.000000 – 0.360	0.0600	2.70	1.89 – 3.51	0.270	COI
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	740657	0.180	0.000000 – 0.360	0.0600	2.31	1.62 – 3.00	0.231	COI
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	783351	0.180	0.000000 – 0.360	0.0600	2.24	1.57 – 2.91	0.224	COI

Figure 3 – Roche PreciControl Toxo IgM lot number 716187 target sheet for Elecsys Toxo IgM reagent lot numbers 712936, 740657 and 783351 when tested on the cobas e 801 analyser.

VS04618866190_756887e801V3

PreciControl Toxo IgM



REF 04618866190

LOT 774051 Ver.3

🕒 2025-01

cobas e 801 analyzer

Value sheet

Component	Method	LOT	PreciControl Toxo IgM level 1 LOT 756887			PreciControl Toxo IgM level 2 LOT 756888			Unit
			Value	Range	1SD	Value	Range	1SD	
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	740657	0.180	0.000000 – 0.360	0.0600	2.76	1.93 - 3.59	0.276	COI
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	783351	0.180	0.000000 – 0.360	0.0600	2.33	1.63 - 3.03	0.233	COI
TOXOIGM	Elecsys Toxo IgM 07028024 ACN 10016	799708	0.180	0.000000 – 0.360	0.0600	2.03	1.42 – 2.64	0.203	COI

Figure 4 – Roche PreciControl Toxo IgM lot number 774051 target sheet for Elecsys Toxo IgM reagent lot numbers 740657, 783351 and 799708 when tested on the cobas e 801 analyser.