The use of ViraQ Check Controls for qualitative and quantitative NAT

SANBS
South African National Blood Service

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Outline

- Ultrio Plus data (2012-2014)
  - Example: S/CO distribution on ViraQ HCV Check 125 control
- Ultrio Elite data (2017-2018)
  - S/CO distribution on ViraQ HBV, HCV and HIV-1 Check 125 controls
    - over time
    - per Panther instrument
    - per Ultrio Elite Master Lot
- Abbott real time PCR data (2017-2018)
  - Viral load data on ViraQ HBV and HIV-1 Check 125 controls
  - Proportion of HIV NAT yields quantifiable by qPCR
- Conclusions

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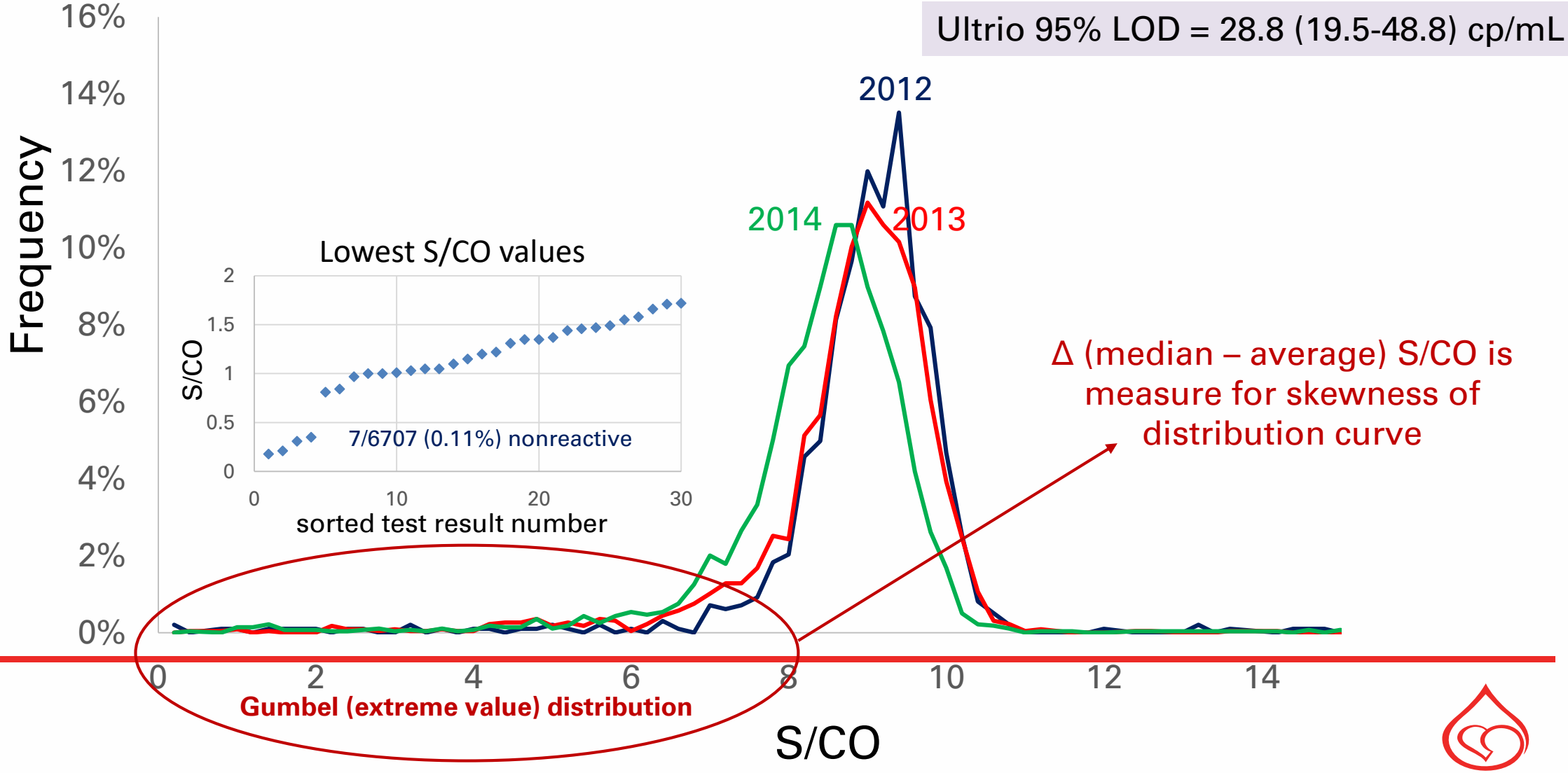
Annual distributions of Ultrio Plus S/CO values (n=6707) on P0063 ViraQ HCV Check 125 control



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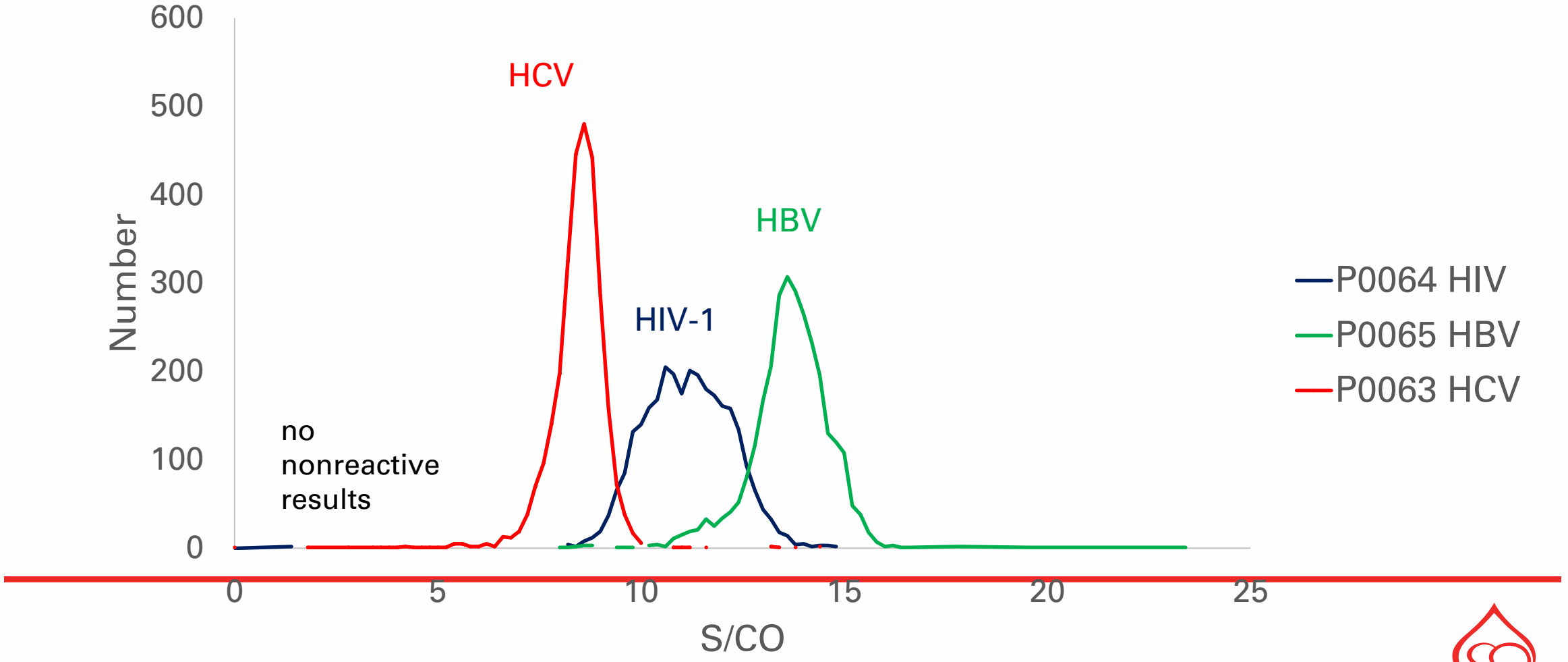
Distribution of Ultrio Elite S/CO values (n=2904) on ViraQ HBV, HCV and HIV-1 Check 125 controls

from January 2017 to February 2018



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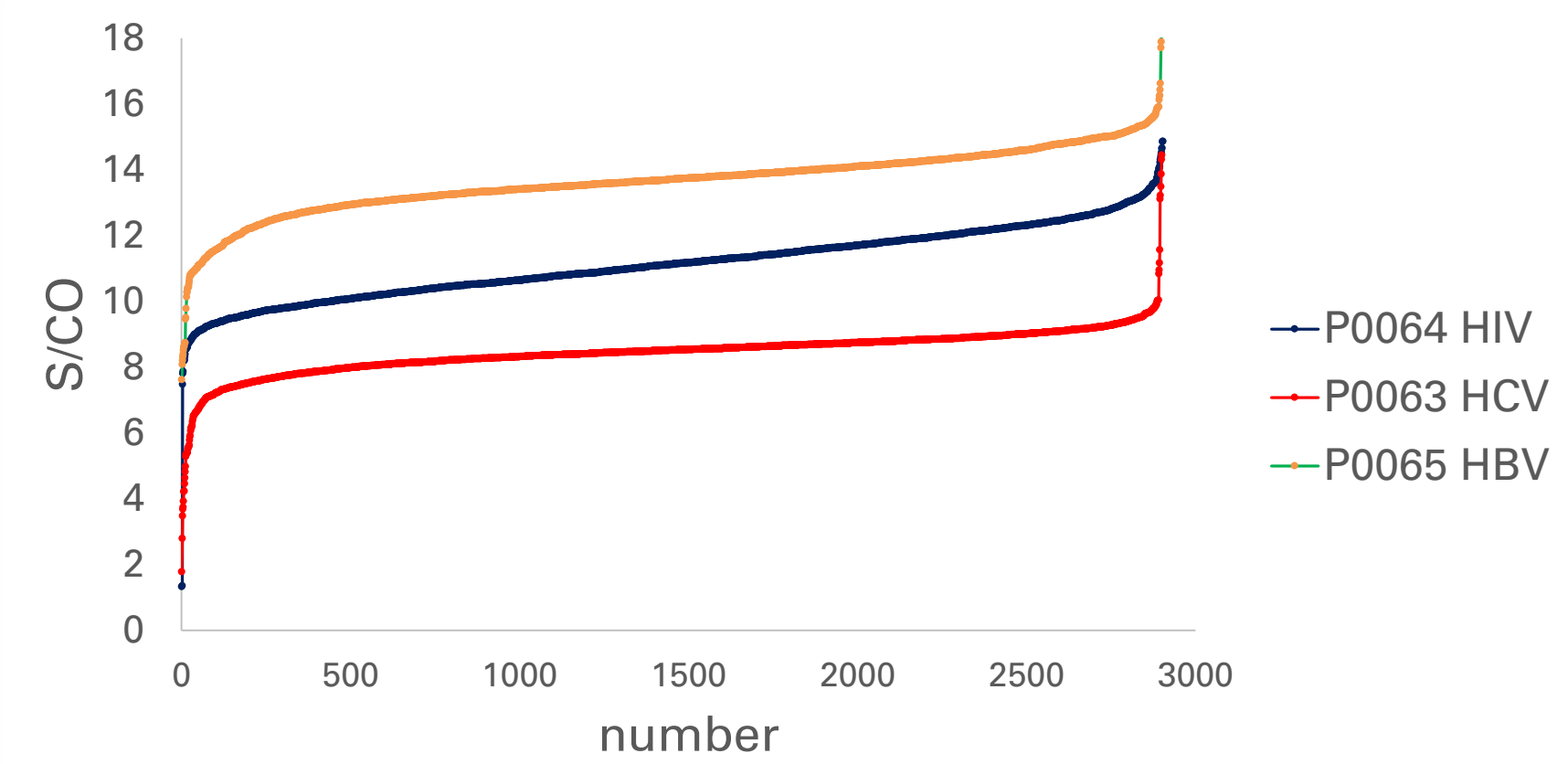
Cumulative distribution of Ultrio Elite S/CO values on ViraQ Check 125 controls



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Predicted and observed Ultrio Elite reactivity rates on ViraQ Check 125 cp/mL controls

ViraQ Control	Predicted response rate per 1000 tests according to product insert			Observed response rate per 1000 tests in evaluation period		
	reactive.	weakly reactive#	nonreactive	reactive	weakly reactive#	nonreactive
P0064 HIV	997	3	0	998	1.7	0
P0065 HBV^	*(985)*	*(15) **	*(0)*	943	57*	0
P0063 HCV	937	62	1.1	977	23	0

Threshold S/CO values for weakly reactive results are < 12.0, 7.0 and 8.0 for HBV, HCV and HIV-1 respectively.

* Difference in proportion weakly reactives was not significant [4.2% (-5.1 to 17.5%)]

^ predicted rates estimated on limited historical data set (n=336)

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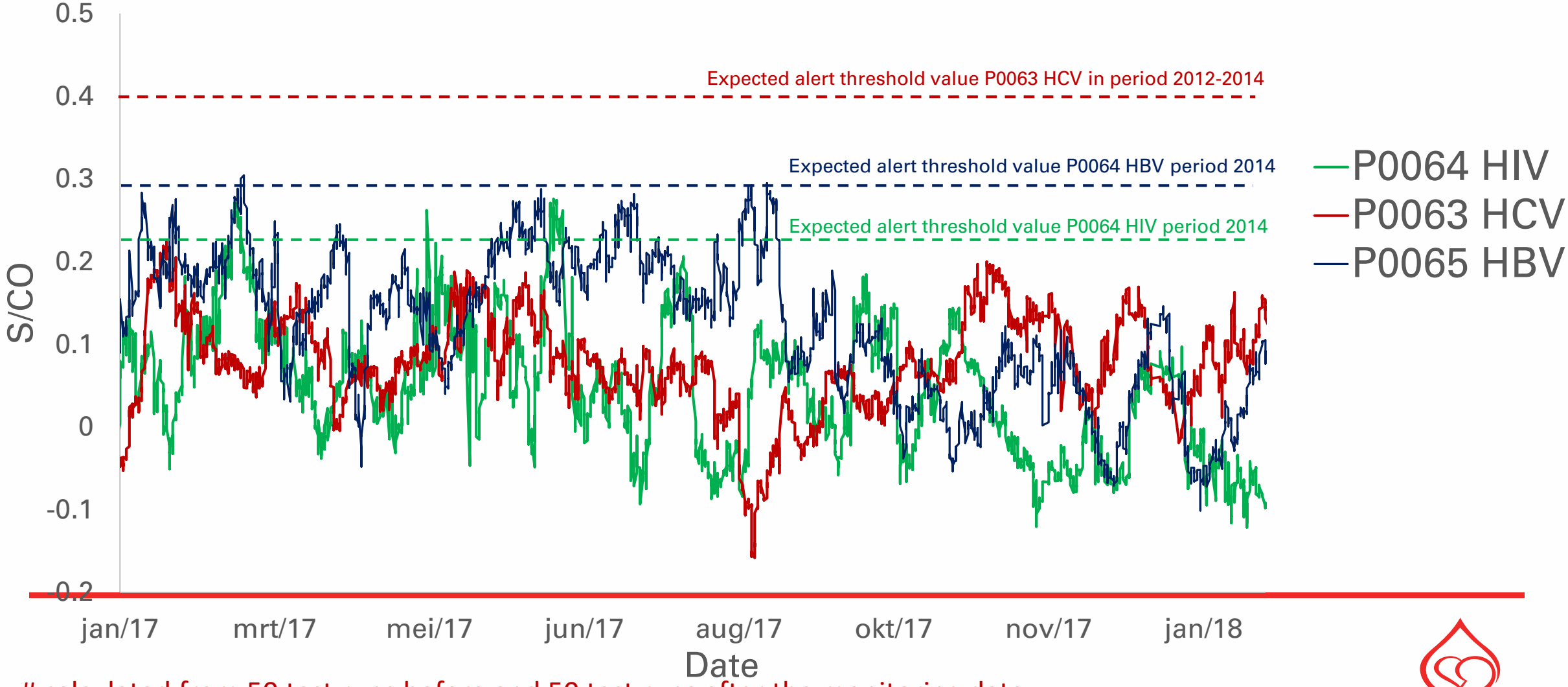
Sliding Δ (median – average) Ultrio Elite S/CO value# on ViraQ Check 125 controls



calculated from 50 test runs before and 50 test runs after the monitoring date

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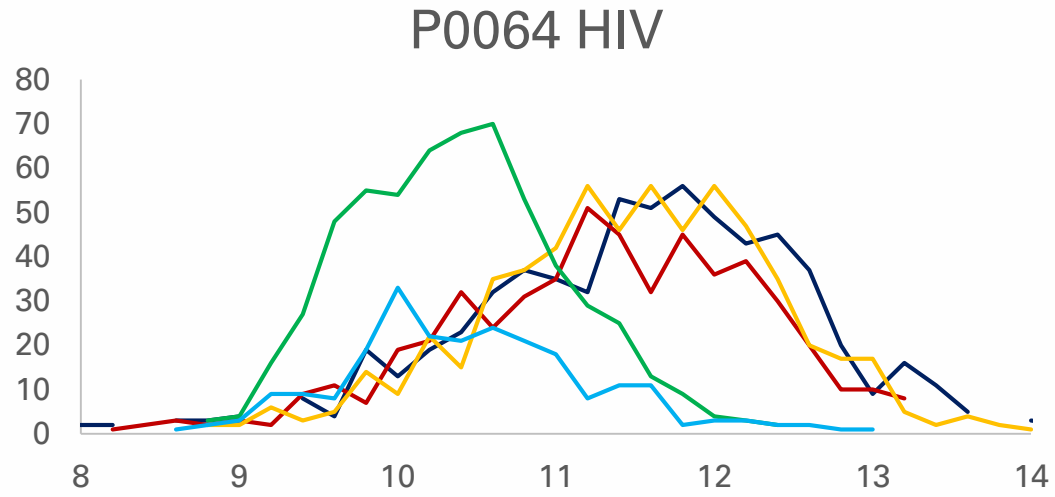
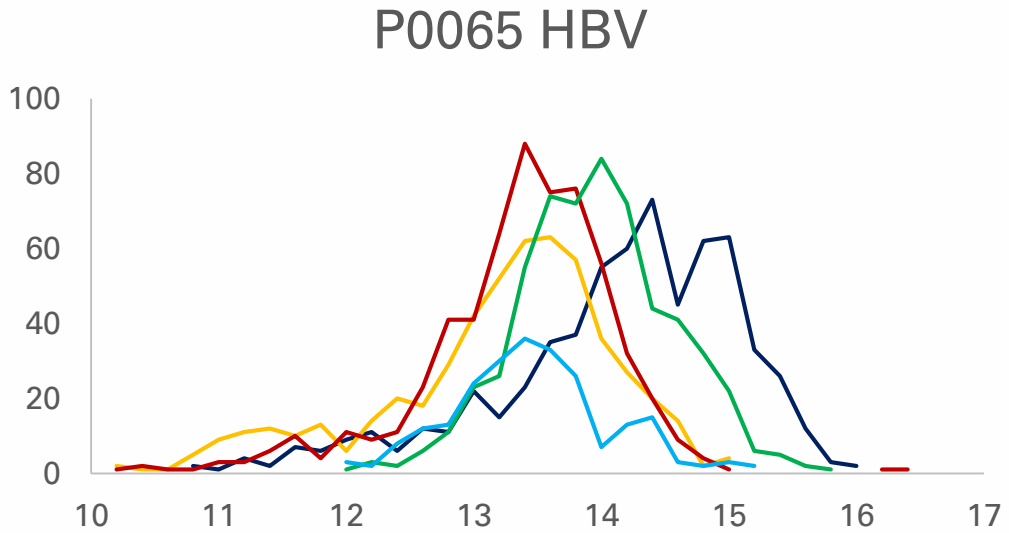
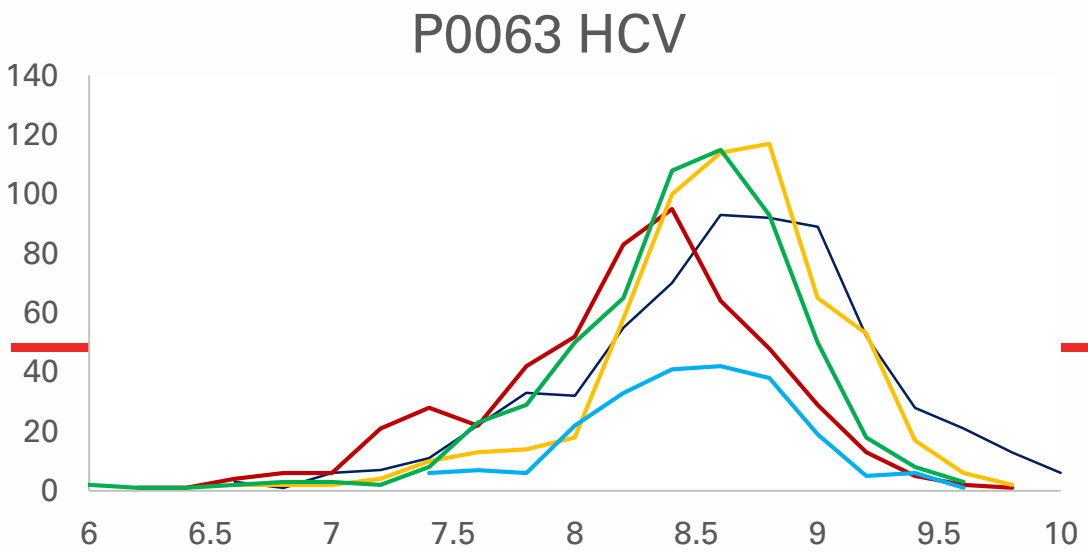
Distribution of S/CO values on ViraQ Check 125 controls by Ultrio Elite Master Lot







Master Lots	tests
154471	734
159260	598
171962	632
180939	670
186731	270

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Delta (median – average S/CO) by Ultrio Elite Master Lot

Master Lot	n	HIV			HBV			HCV		
		median	average	delta	median	average	delta	median	average	delta
154471	734	11.70	11.63	0.07	14.35	14.18	0.17	8.70	8.62	0.08
159260	598	11.42	11.35	0.07	13.42	13.23	0.19	8.32	8.22	0.10
171962	632	11.53	11.47	0.05	13.43	13.32	0.10	8.63	8.60	0.03
180939	670	10.34	10.34	-0.01	13.93	13.89	0.04*	8.47	8.37	0.10
186731	270	10.43	10.49	-0.06	13.41	13.39	0.01*	8.44	8.34	0.10

* Lower values indicative of higher analytical sensitivity

lower values than in 2012-2014

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Delta (median – average S/CO) by Panther instrument

Panther instrument	n	HIV			HBV			HCV		
		median	average	delta	median	average	delta	median	average	delta
438	360	11.35	11.30	0.05	13,76	13,83	-0.07	8.55	8.57	-0.02
1237	373	11.32	11.27	0.05	13,87	13,87	0.00	8.59	8.54	0.05
1427	367	11.02	11.05	-0.03	13,59	13,67	-0.08	8.46	8.41	0.05
1428	371	10.88	10.98	-0.10	13,59	13,52	0.07	8.29	8.24	0.05
1429	363	11.51	11.48	0.03	14,00	14,06	-0.06	8.70	8.69	0.01
1430	377	11.28	11.29	-0.01	13,89	13,89	0.00	8.71	8.66	0.05
1433	358	10.27	10.33	-0.06	12,64	12,59	0.05	7.98	7.96	0.01
1434	335	11.42	11.37	0.05	13,81	13,81	0.00	8.54	8.52	0.02

No differences between instruments were observed

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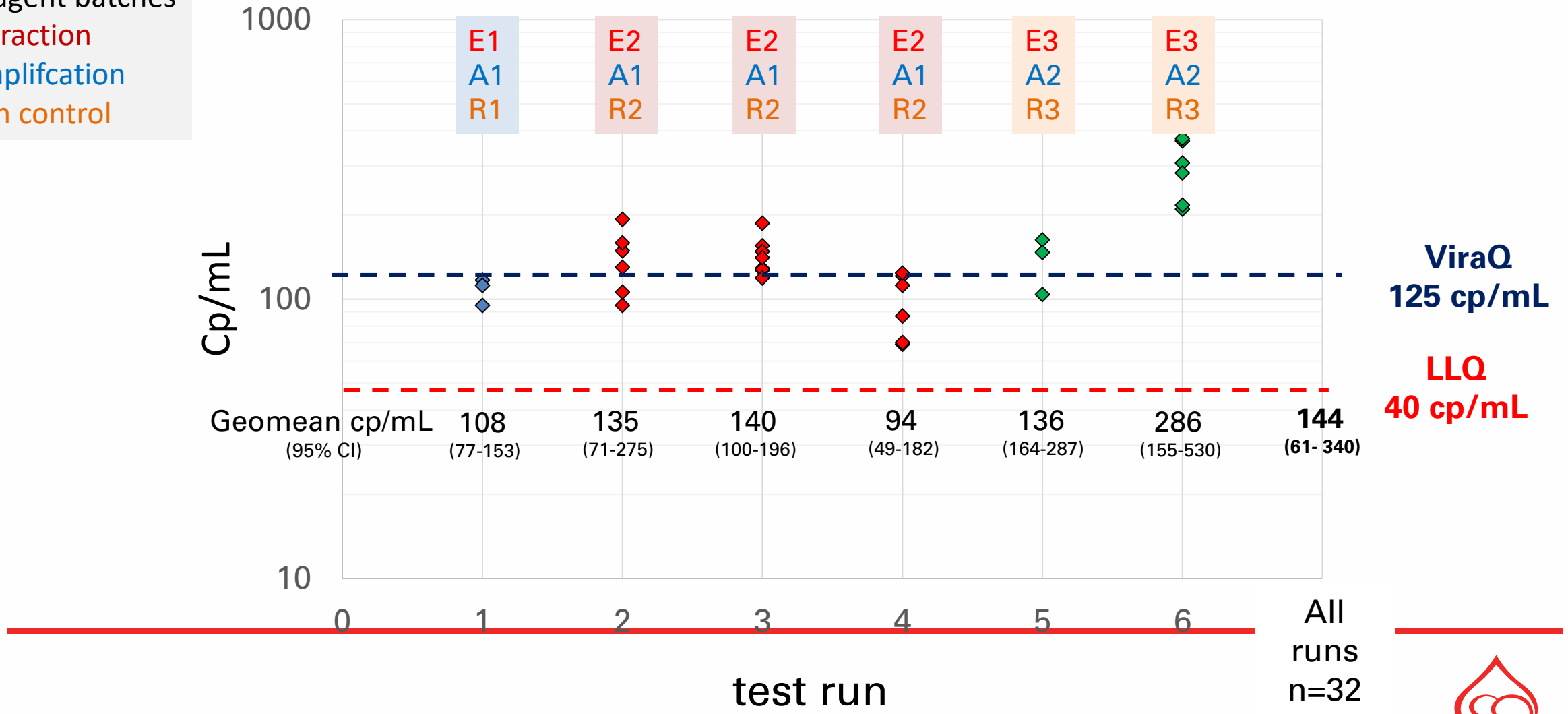
Quantification of ViraQ HIV-1 Check 125 Control in Abbott Real Time PCR Assay



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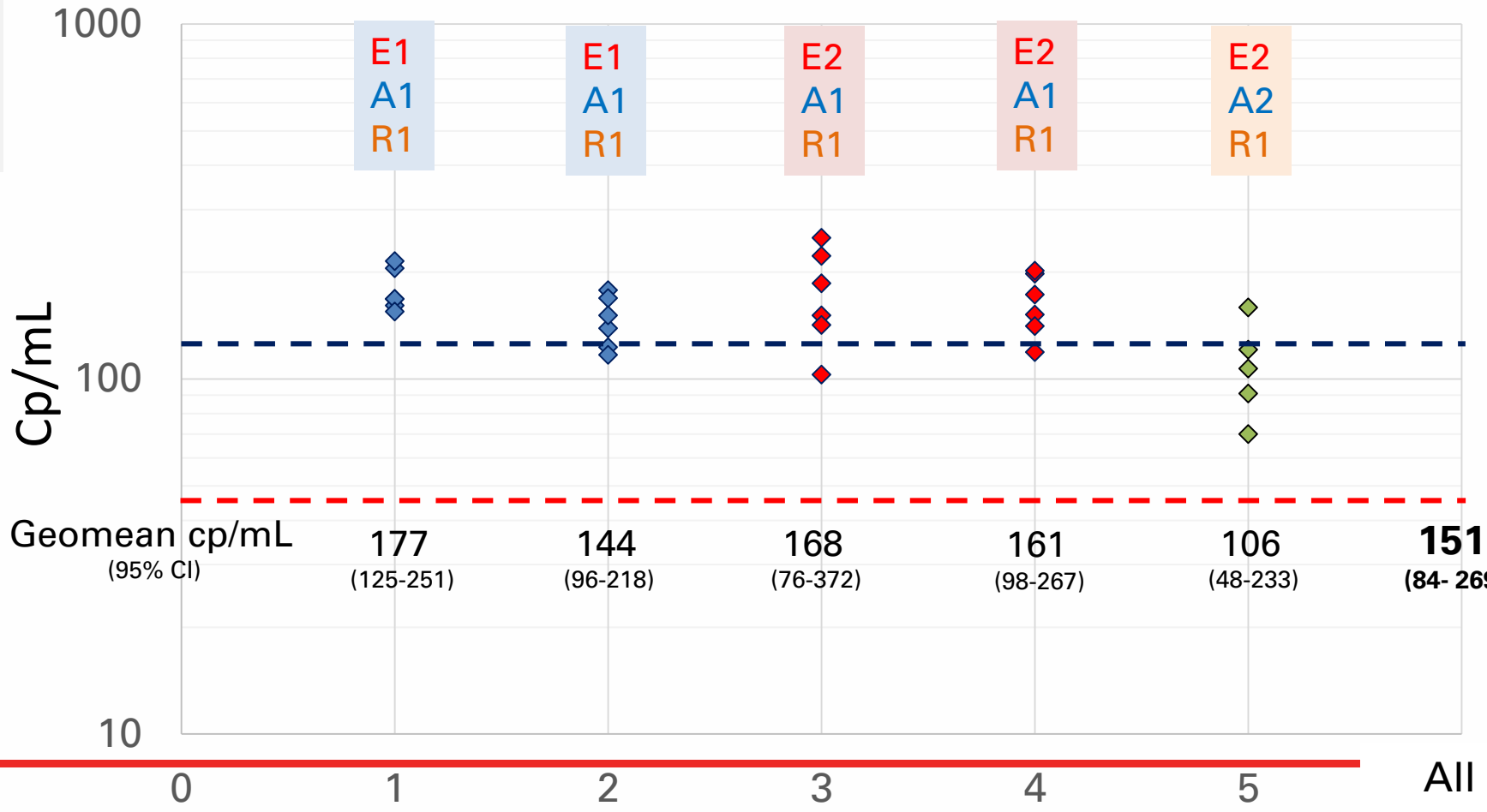
Quantification of ViraQ HBV Check 125 Control in Abbott Real Time PCR Assay

Reagent batches
Extraction
Amplifcation
Run control



ViraQ
125 cp/mL^

LLQ
34 cp/mL#

Abbott: 1 IU = 3.41 copies
^BioQControl: 1 IU = 5.33 copies

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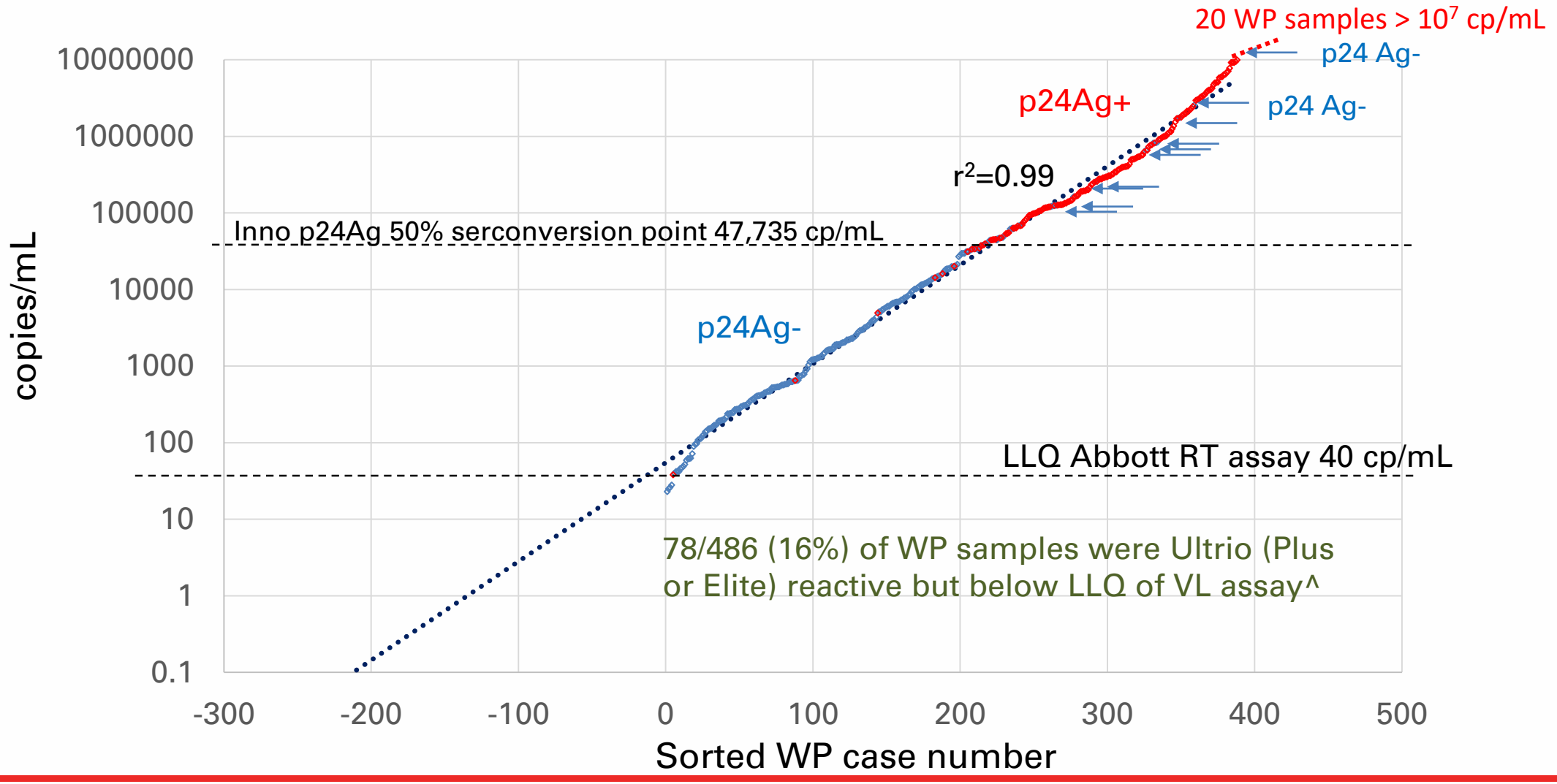
Viral load distribution in HIV WP donations



VL can be estimated by probit analysis using reactivity rate by replicate tests on WP sample and on HIV-1 subtype C standard dilution panels [Vermeulen et al. Transfusion 2013;53:2384-2398]

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Conclusions

- ViraQ Check controls of 125 cp/mL at 3-6 times 95% LOD are instrumental to ensure sufficient analytical sensitivity of Ultrio Plus and Elite test assays
- ViraQ Trend Controls of 25 cp/mL near 95% LOD are currently used for Ultrio Elite Master Lot acceptance testing (data not shown)
- Delta (Median – Average) S/CO can be used to monitor trends in analytical sensitivity of Ultrio Elite test runs, Master Lots and Panther instruments
- ViraQ Check 125 Controls are at sufficient distance to LLQ of Abbott Real Time assay and show variation between test runs and reagent batches
- 16 % of confirmed HIV NAT yields have VL below LLQ of Abbott Real Time Assay.
- VL's on WP samples below LLQ of qPCR assay can be determined by replicate NAT testing and comparison of reactivity rates on BioQ viral standard dilution panels by probit analysis^

^Vermeulen et al. Transfusion 2013;53:2384-2398
^Vermeulen et al. Transfusion 2014;54:2496-2504

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Thank you