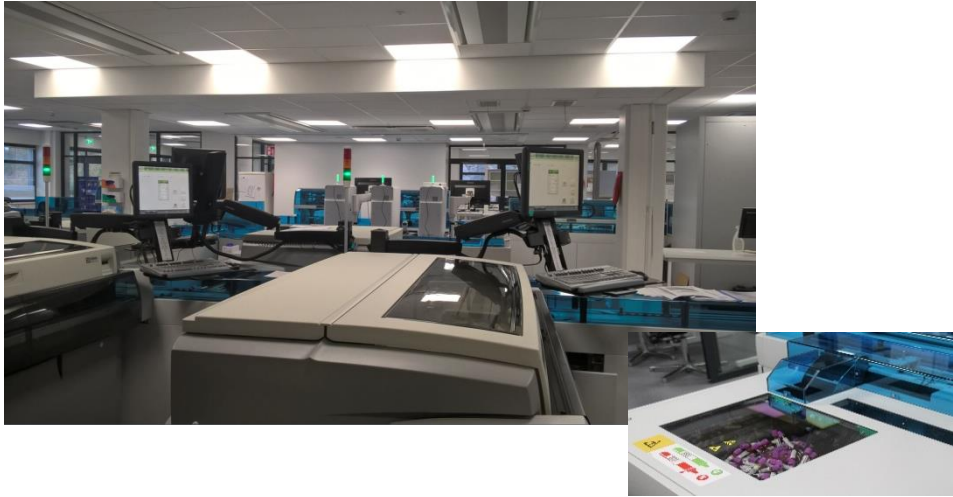


MONITORING PARVO B19V VIRAL LOAD IN PROCLEIX ASSAYS ON TIGRIS AND PANTHER PLATFORMS USING VIRAQ RUN CONTROL

15.5.2018 Heli Tenkanen

Blood donor sample screening

≈800 donations



Pre-analytics

Automation laboratory
Flexlab track
ParthFinder sorter



Serological screening

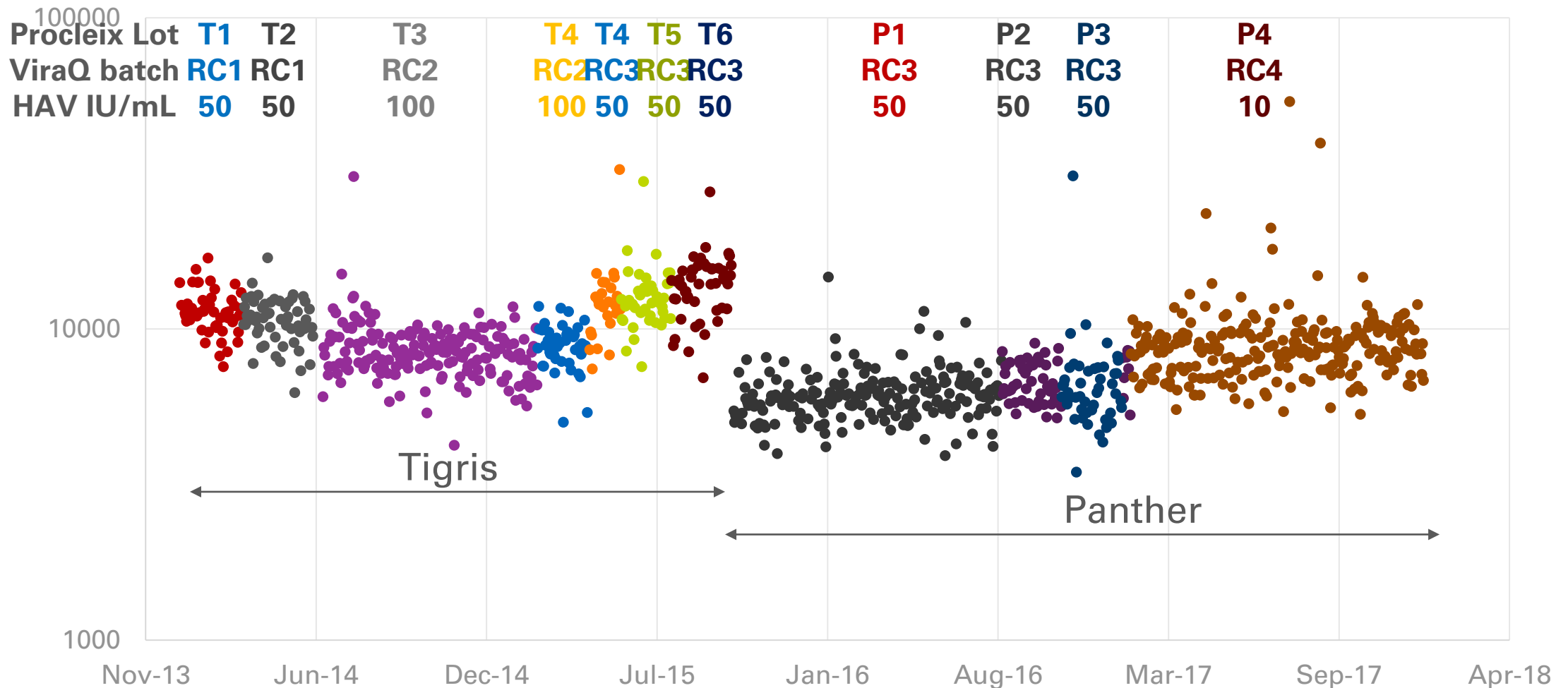
HIV Ag/Ab, HBsAg, HCVAb,
SyphilisAb
Architects connected to track



NAT screening

ID-NAT HIV/HBV/HCV
Pool NAT HAV/Parvo B19

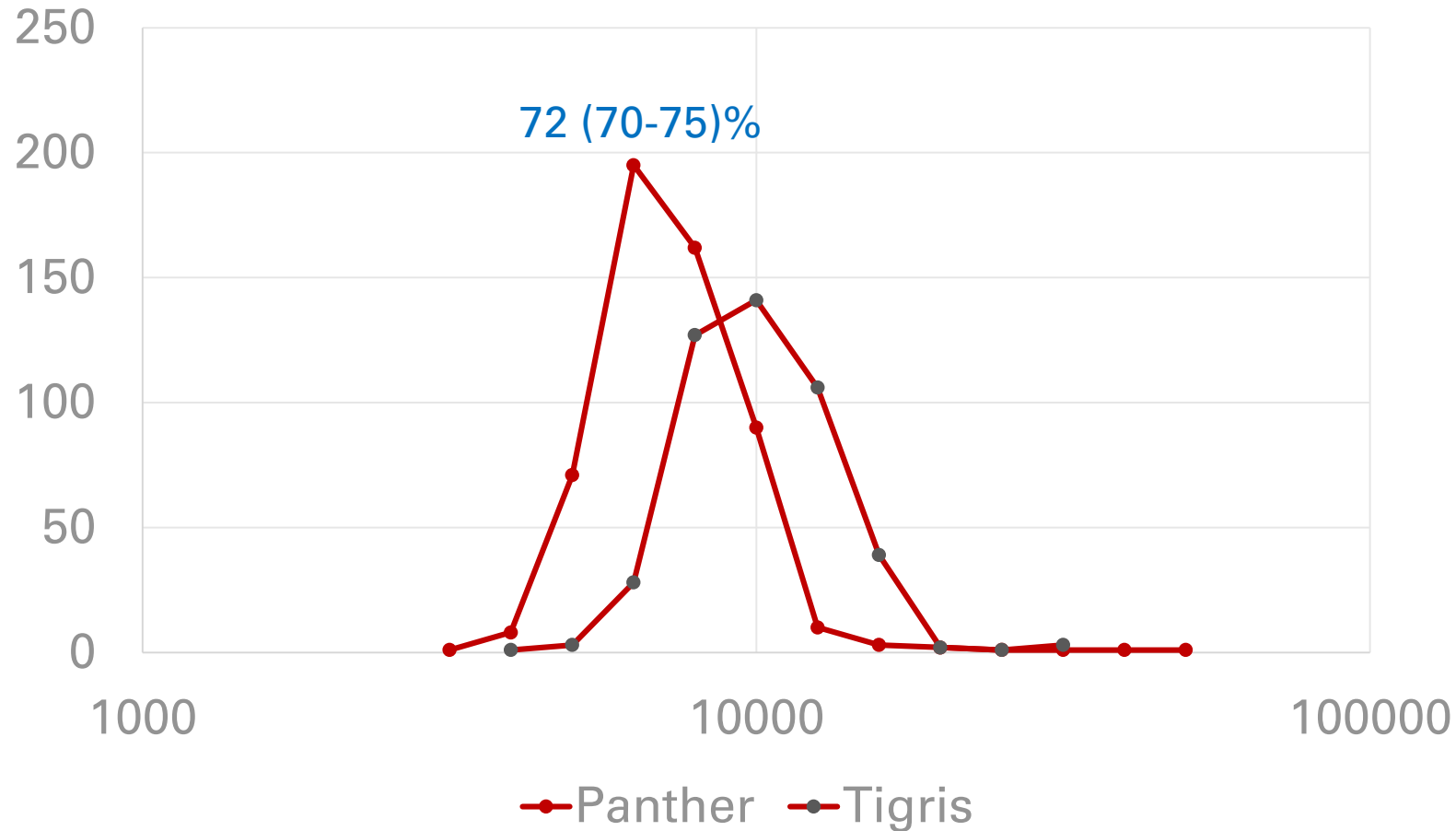
Quantification of ViraQ parvo B19V 10.000 IU/mL Control in Procleix assay runs over 4 year period



Quantification of ViraQ parvo B19V 10.000 IU/mL Control in Procleix assay runs over 4 year period per reagent lot

Instrument	period	n	NAT Lot	Run Control batch	B19V/HAV IU/mL	Geomean IU/mL (95%CI)
Tigris	01/01/14 - 14/03/14	52	T1	RC1	10,000/50	11,283 (7813 – 16,296)
	17/03/14 - 18/06/14	57	T2	RC1	10,000/50	10,560 (7076 -15,843)
	18/06/14 - 24/02/15	180	T3	RC2	10,000/100	8435 (5355 – 13,289)
	25/02/15 - 24/04/15	42	T4	RC2	10,000/100	8722 (5823 – 13,064)
	27/04/15 - 02/06/15	25	T4	RC3	10,000/50	12,020 (6079 – 23,764)
	03/06/15 - 31/07/15	43	T5	RC3	10,000/50	12,465 (7502 – 20,712)
	01/08/15 - 10/10/15	49	T6	RC3	10,000/50	13,532 (7902 – 23,173)
Panther	13/10/15 - 22/08/16	201	P1	RC3	10,000/50	6081 (4045 - 8142)
	23/08/16 - 31/10/16	49	P2	RC3	10,000/50	6749 (4787 - 9516)
	01/11/16 - 10/01/17	47	P3	RC3	10,000/50	6486 (3136 – 13,416)
	11/01/17 - 20/01/17	8	P4	RC3	10,000/50	7272 (4330 – 12,215)
	21/01/17 - 30/12/17	241	P4	RC4	10,000/10	8707 (4845 – 15,621)

Distribution of IU/mL values[^] reported by two Procleix parvo B19V/HAV assay versions on ViraQ 10,000 IU/mL Control#



[^]448 Tigris runs and 546 Panther runs in period between January 2014 to December 2017 reported by FRC, Finland
 #Dilution of VQC-Sanquin standard that is directly traceable to 1st WHO 99/800 standard

Opposite change in quantification of WHO parvo B19V 12/208 IS and ViraQ Control with introduction of new Procleix assay version

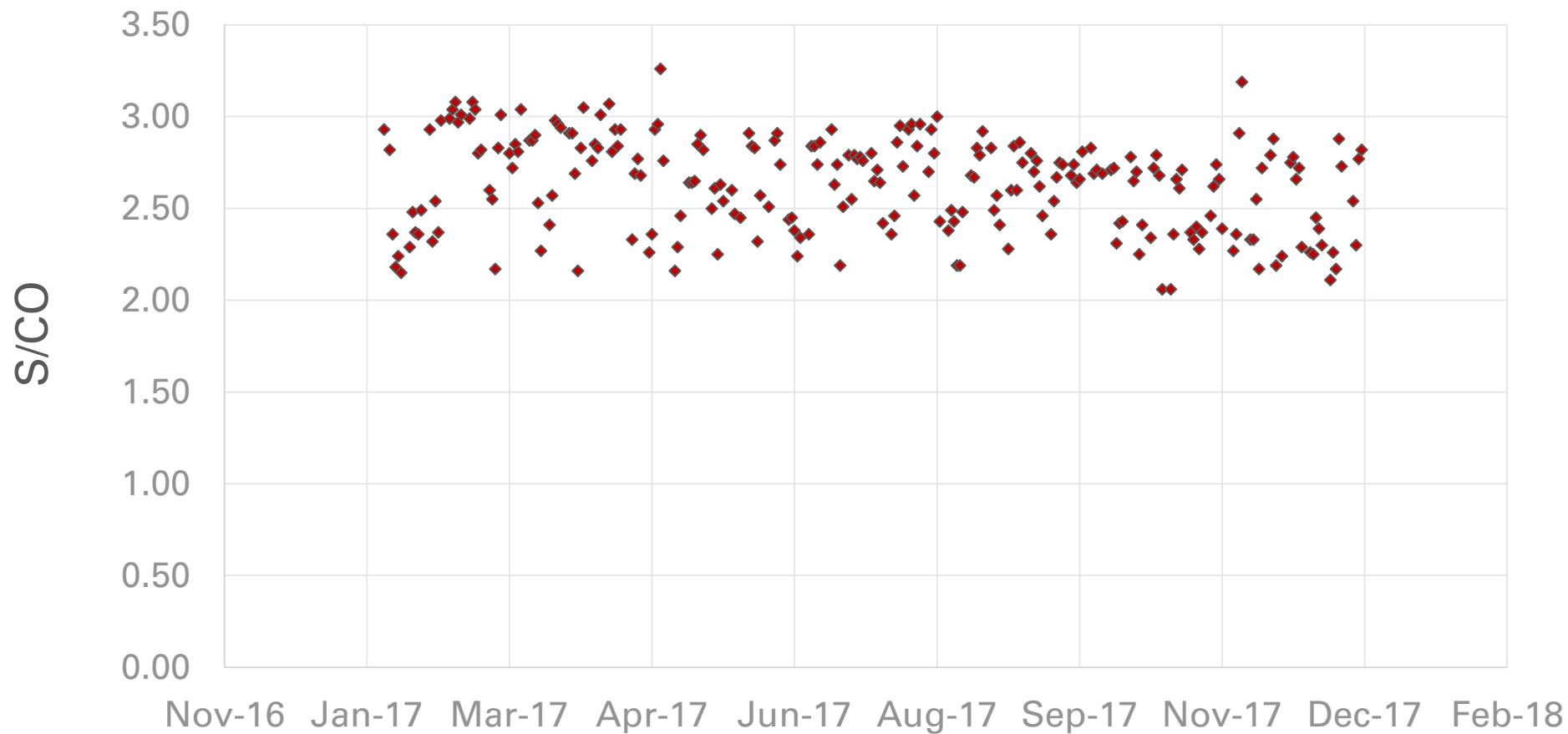
3 rd WHO IS IU/mL	Tigris# n=2	Panther# n=2	factor
600	702	1034	1.47
1000	750	1571	2.09
3000	3463	5250	1.52
10000	12740	14893	1.17
30000	36649	68706	1.87
Geomean factor ^{\$} =1.59			
ViraQ RC IU/mL	Tigris^ n=201	Panther^ n=49	factor
10000	13532	6081	0.45

FRC validation data September 2015

^ run control data on last master lot 131513 on Tigris and first lot 142814 on Panther

\$ factor in Grifols package insert = 1.56 fold (240 data points)

Procleix HAV response values in Panther on P0266 ViraQ parvo B19/HAV (10,000/10 IU/mL) run control



NRL EQAS: FRC results 2016-2017

Round	Sample	FRC Panther	Expected results		FRC Panther	Expected results
		PVB19	PVB19	PVB19	HAV	HAV
		log IU/ml	log IU/ml	Qualitative Interpretation	S/Co	Qualitative Interpretation
16.3.2016	A	>5	5,91	Detected	2,43	Detected
	B	<2,69	N/A	Not Detected	2,88	Detected
	C	<2,69	N/A	Not Detected	0,13	Not Detected
	D	>5	5,90	Detected	0,00	Not Detected
	E	>5	4,84	Detected	0,06	Not Detected
22.6.2016	A	>5	7,00	Detected	0,11	Not Detected
	B	<2,69	N/A	Not Detected	0,18	Not Detected
	C	<2,69	N/A	Not Detected	3,17	Detected
	D	<2,69	N/A	Not Detected	3,25	Detected
	E	>5	7,10	Detected	3,02	Detected
28.9.2016	A	5,00	5,85	Detected	0,00	Not Detected
	B	>5	7,07	Detected	2,53	Detected
	C	>5	7,05	Detected	0,13	Not Detected
	D	<2,69	N/A	Not Detected	0,14	Not Detected
	E	<2,69	N/A	Not Detected	2,63	Detected
22.3.2017	A	<2,69	N/A	Not Detected	0,18	Not Detected
	B	>5	6,07	Detected	2,97	Detected
	C	>5	5,99	Detected	0,19	Not Detected
	D	<2,69	N/A	Not Detected	0,18	Not Detected
	E	<2,69	N/A	Not Detected	2,98	Detected
28.6.2017	A	>5	7,06	Detected	0,08	Not Detected
	B	>5	5,02	Detected	0,00	Not Detected
	C	>5	7,08	Detected	1,89	Detected
	D	<2,69	N/A	Not Detected	2,77	Detected
	E	<2,69	N/A	Not Detected	2,84	Detected
27.9.2017	A	<2,69	N/A	Not Detected	3,02	Detected
	B	>5	7,06	Detected	2,87	Detected
	C	>5	5,01	Detected	0,18	Not Detected
	D	>5	5,95	Detected	2,67	Detected
	E	<2,69	N/A	Not Detected	0,17	Not Detected

FRC:Procleix HAV-PARVO

- Pools of 16 samples
- Parvo: Cut-off value 2000 IU/ml
- Parvo: Detection limit 500 IU/ml
- HAV: S/Co ≥ 1
- HAV: Analytical sensitivity 1,28 IU/ml

Discussion

- The migration of the Procleix assay from Tigris to Panther coincided with:
 - 1.59 fold higher quantification of the 3rd WHO Parvo B19V International Standard (12/208) (FRC validation)
 - 1.8-2.2 fold lower quantification of the ViraQ run control batch in use.
- The 3rd WHO Parvo B19V International Standard (12/208) is quantified with:
 - 1.56 fold higher than nominal IU/mL values by the Procleix assay on Panther (Grifols Package Insert)
 - *1.68 fold lower than nominal IU/mL values by the Roche DPX assay (Pisani et al, Vox Sang 2016)*
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- The VQC-Sanquin Parvo B19V genotype 1 standard (used for preparation of ViraQ run controls) has been calibrated against the 1st WHO IS 99/800
- The opposite change in parvo B19V quantification of the 3rd WHO IS (12/208) and the ViraQ run control may be explained by a change in oligonucleotide design of the Procleix Parvo B19V/HAV assay version on Panther.
- The concentration of HAV in VQC control batches may have some effect on the B19V quantification of this control.