

A system for post-market performance follow-up (PMPF) of IVDs for blood screening

Harry van Drimmelen, BioQControl

Pre-IPFA-PEI Satellite Workshop

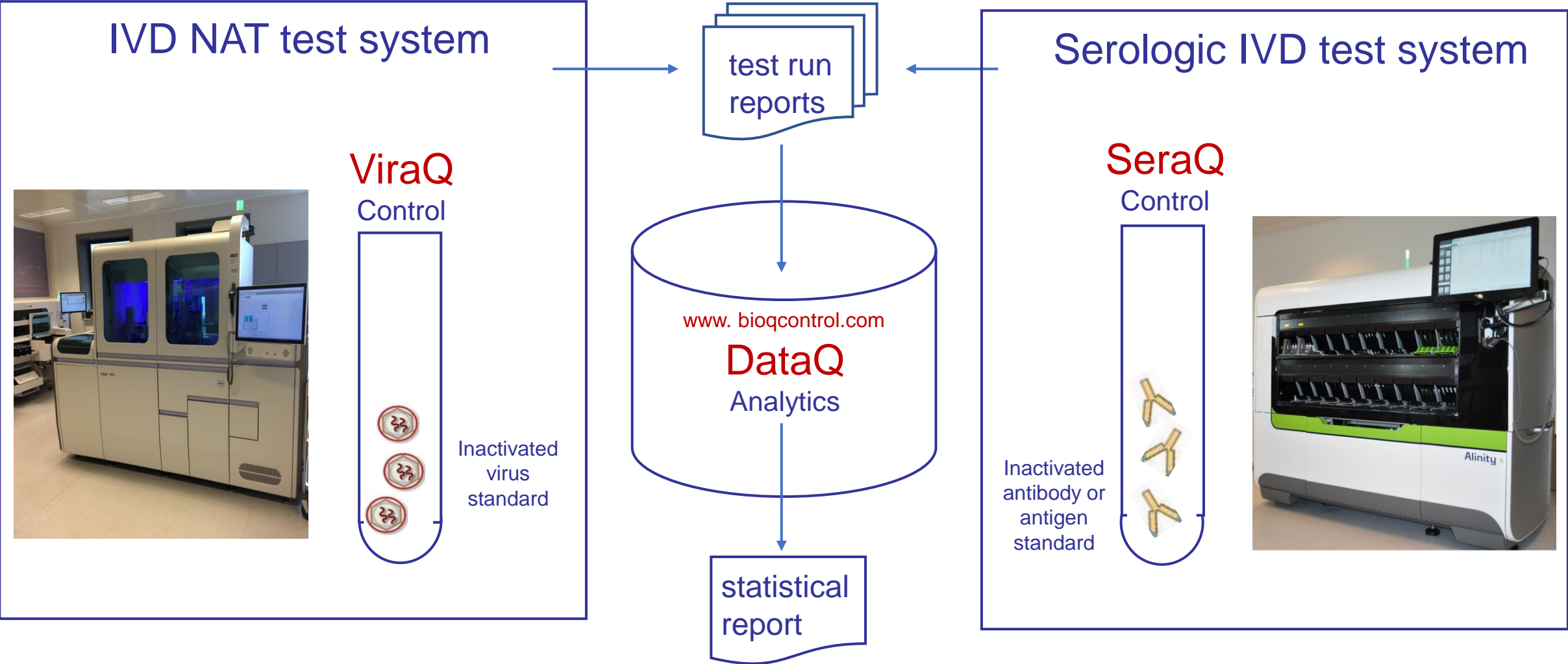
May 9th 2023, Hotel NH Bologna de la Gare

Post-market performance follow-up (PMPF)

(The In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR) and Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act)

PMPF is used to monitor the performance evaluation of IVDs after market approval. The aim is guarding safety, performance and scientific validity, to detect any emerging risks and identify systematic errors.

Post-Market Performance Follow-up (PMPF) system

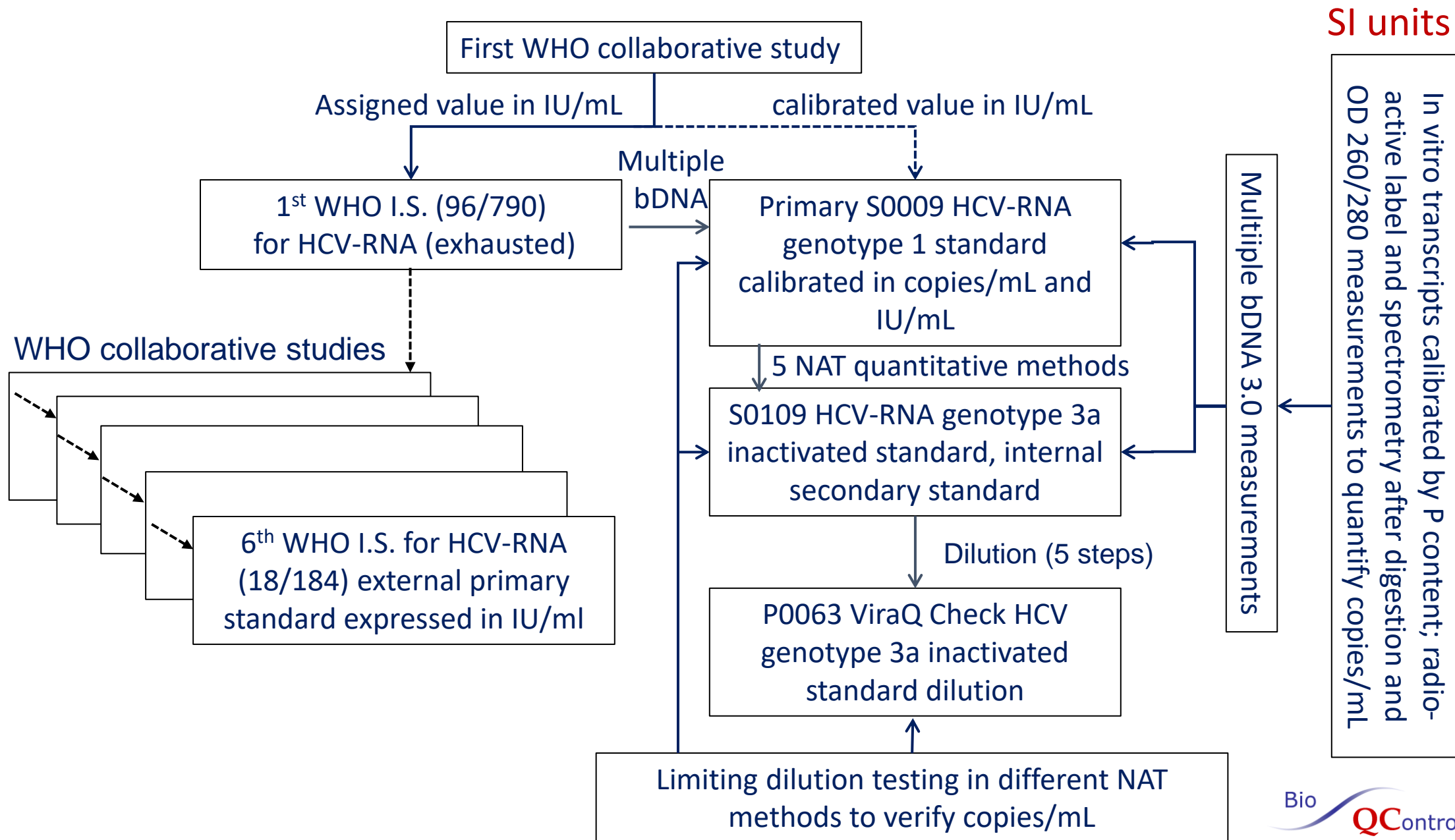


ViraQ and SeraQ Controls are IVD test system specific and ensure sufficient analytical sensitivity

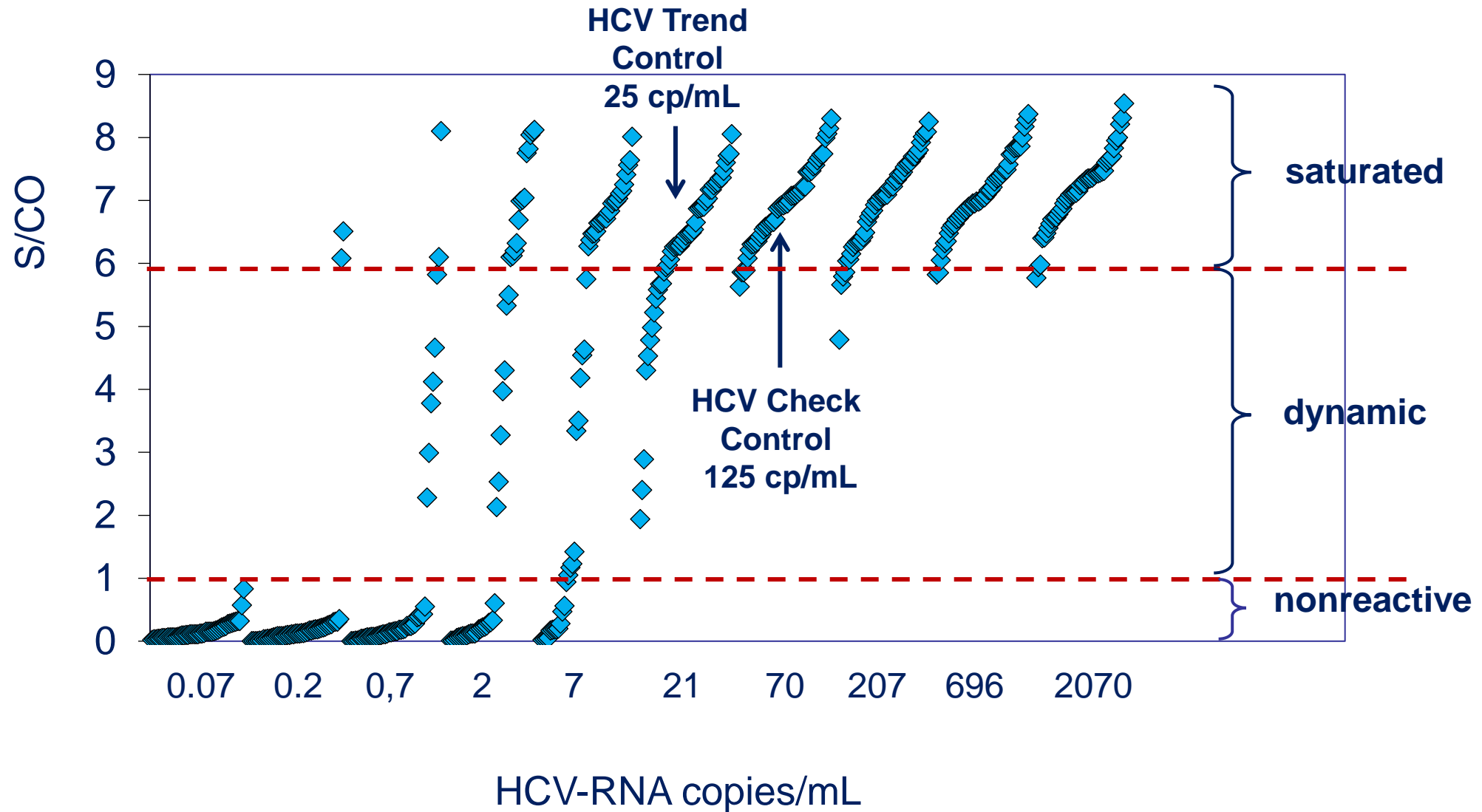
Assay specific design of run controls

- Inactivated source material
 - using validated methods in plasma industry
- Calibrated standard
 - Traceable to SI units (copies/mL in bDNA assay and verified in limiting dilutions)
 - Traceable to first WHO standards (IU/mL)
- Optimal concentration
 - SeraQ 2.2-3.5 x cutoff
 - ViraQ Check 4-5 (3-10) x 95% LOD
 - ViraQ Trend 1-2 x 95% LOD
- Product lifetime
 - Sufficient source material for >10 years
- Product stability
 - Open shelf life (ViraQ 8 hours, SeraQ 1 week)
 - Storage conditions (ViraQ 2 year -30°C, SeraQ 5 year -20°C)
 - Transport conditions (dry ice -79°C)

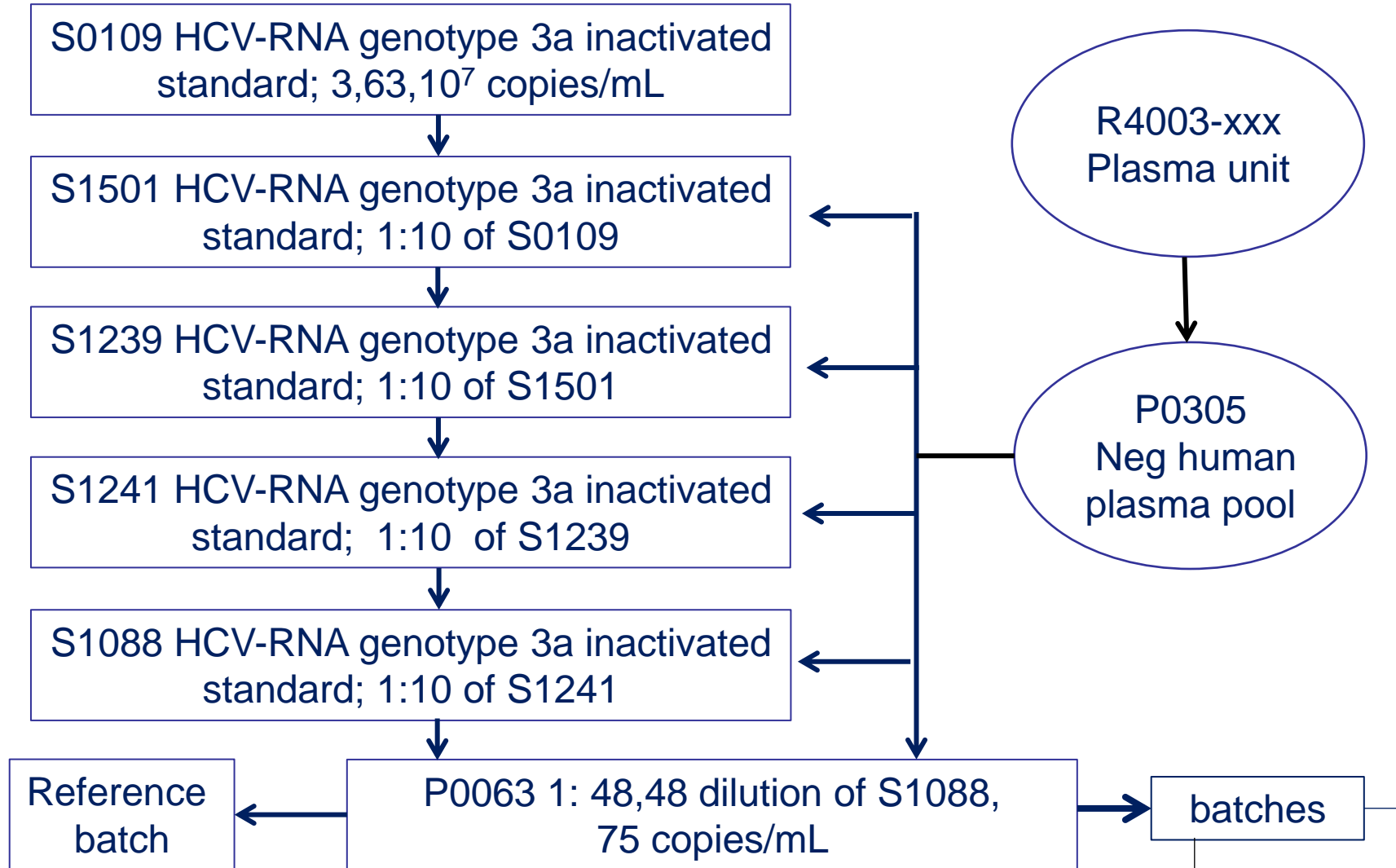
Calibration of S0109 HCV standard used in ViraQ Controls



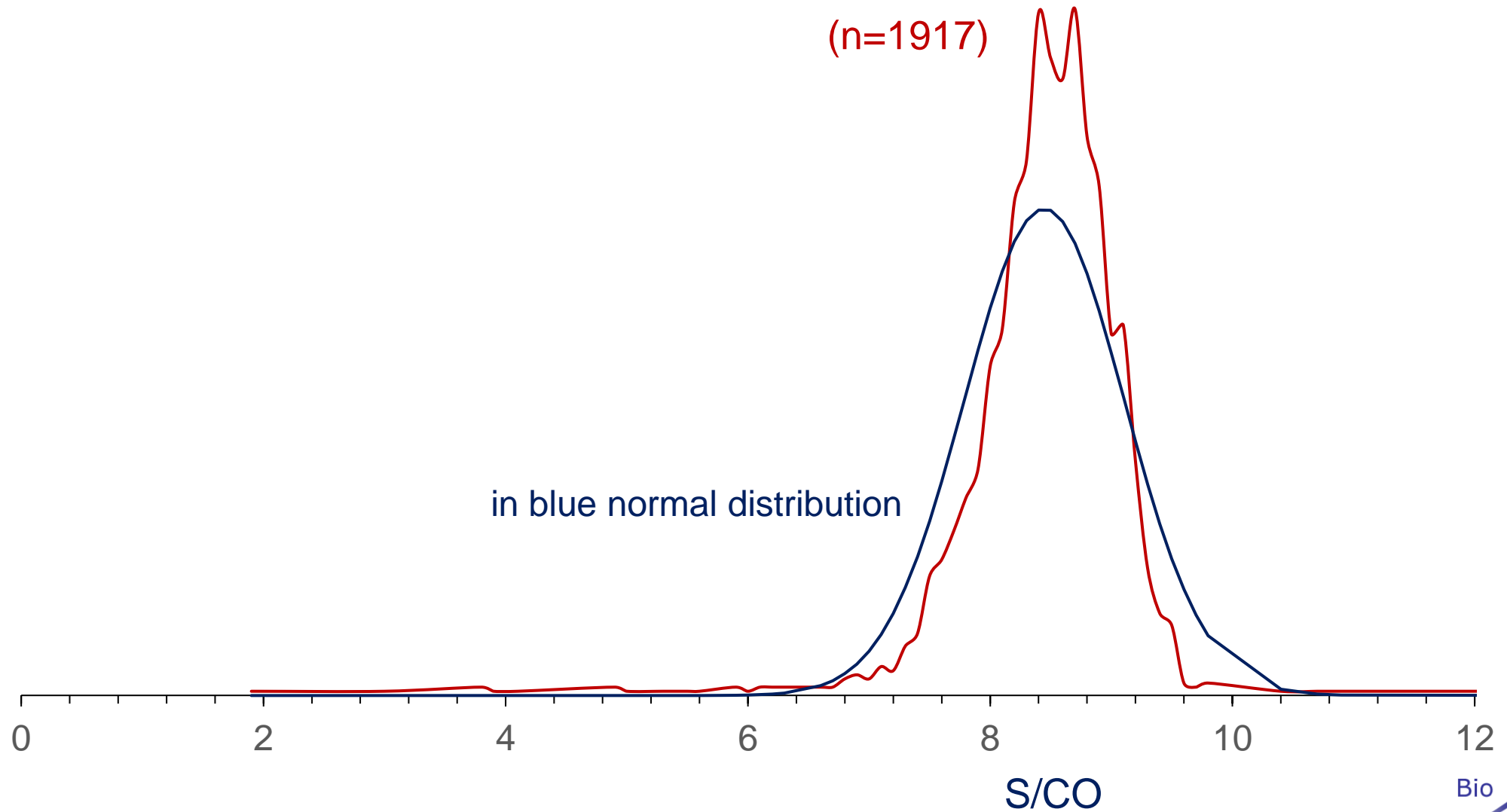
S/CO distribution of Ultrio assay on inactivated HCV-RNA standard dilution panel



Manufacturing trail of P0063 ViraQ HCV Check 125



Distribution S/CO ratios of Ultrio Elite on P0063 ViraQ HCV Check 125

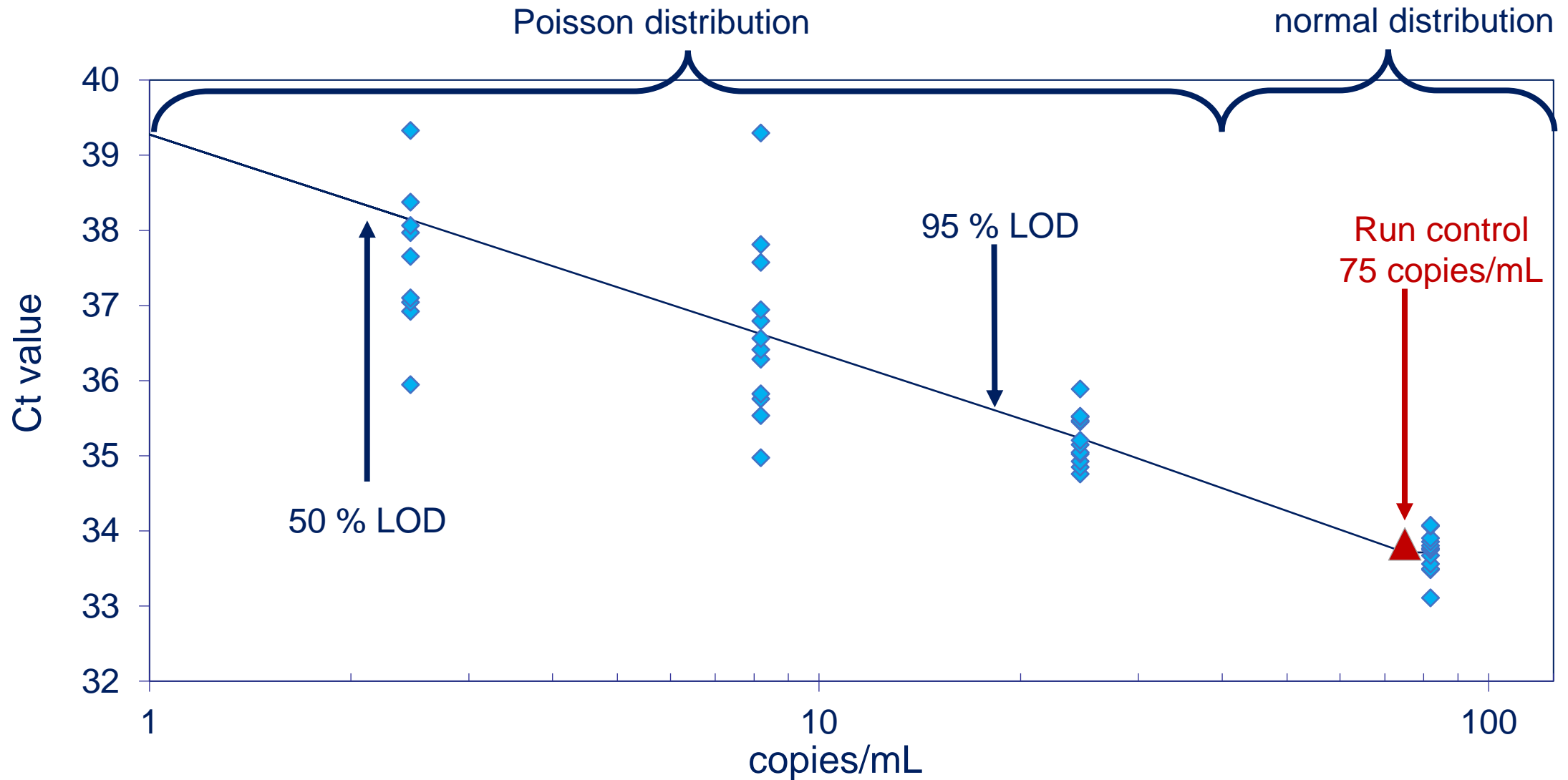


ViraQ Check vs Trend Controls in Procleix tests

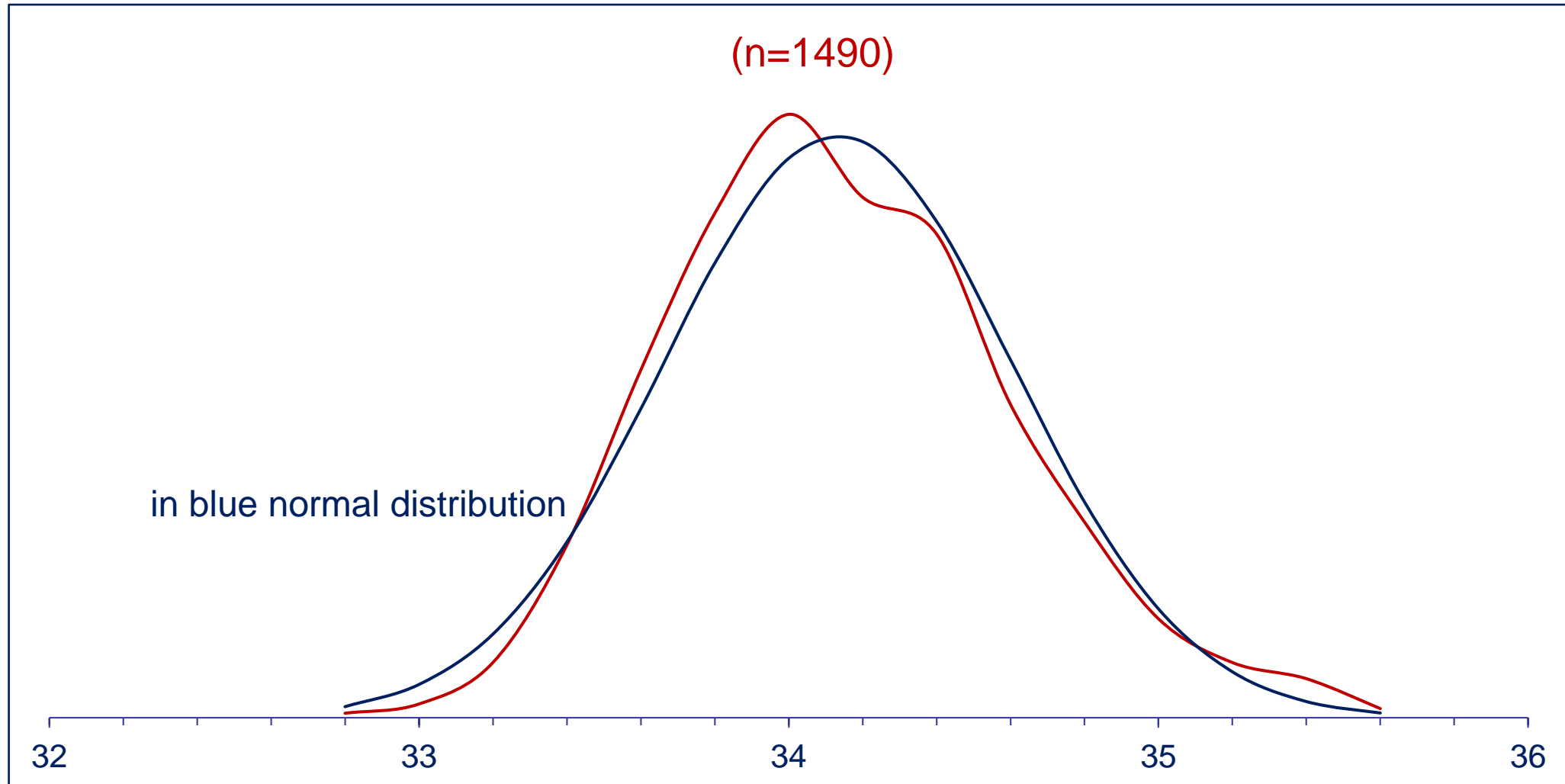
Requirement	Check control	Trend control
Reactivity	99.9-100%	95-99%
Recognition of decrease in analytical sensitivity	No; unless >2-fold decrease	Yes; S/CO will decrease immediately
Difference between mean and median	Limited	Sensitivity parameter
95 and 99 % predictive limits	Stable	Volatile
CLIA regulations	Fulfilled	Not fulfilled
Useful for test run release	Yes	No
Comparison of test reagent lots and run control batches	No	Yes

Conclusion: Use Check Controls in every test run and Trend Controls at certain intervals

Ct values of Roche Cobas MPX on HBV genotype A (inact.) standard dilution panel



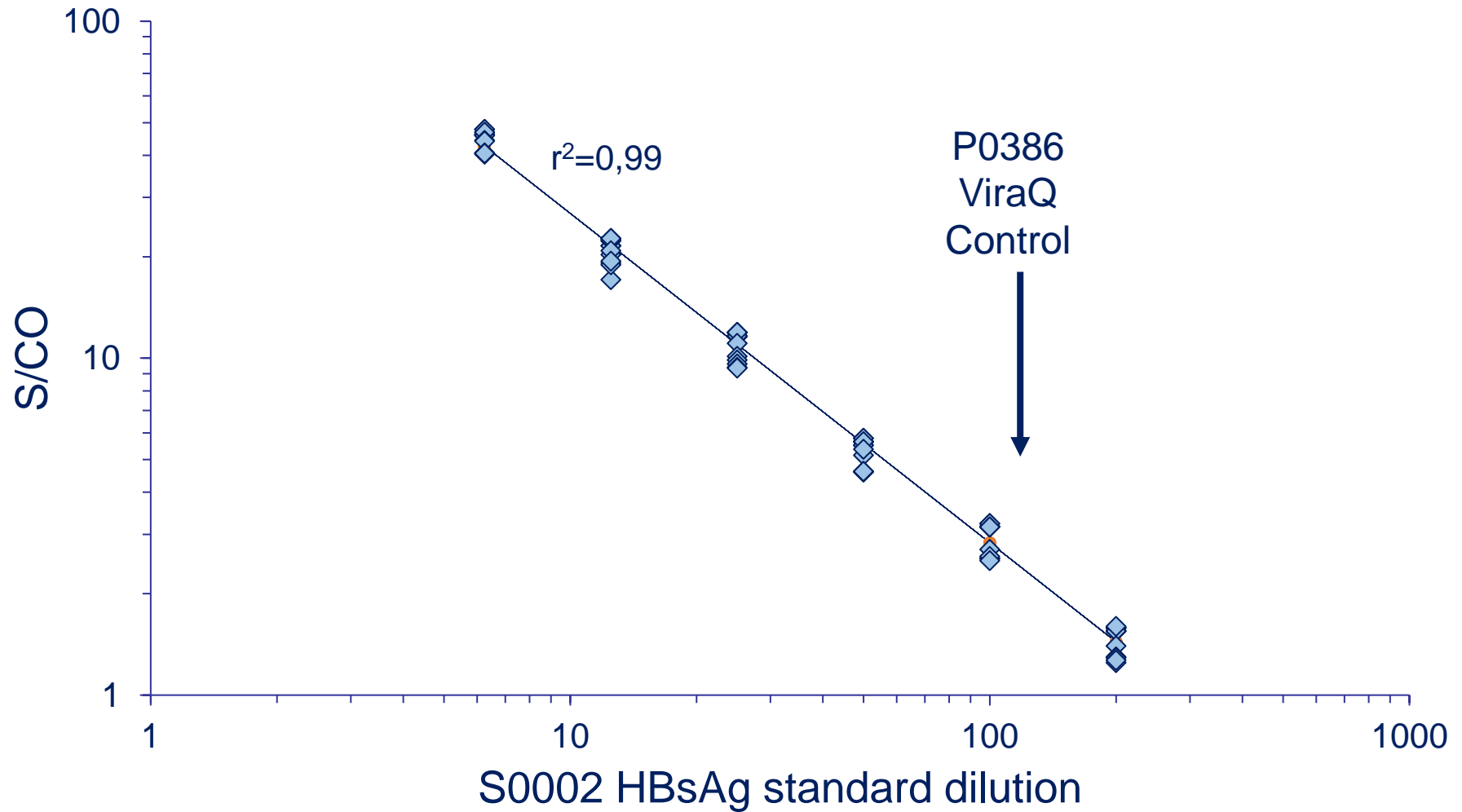
cobas MPX HBV-DNA Ct value distribution



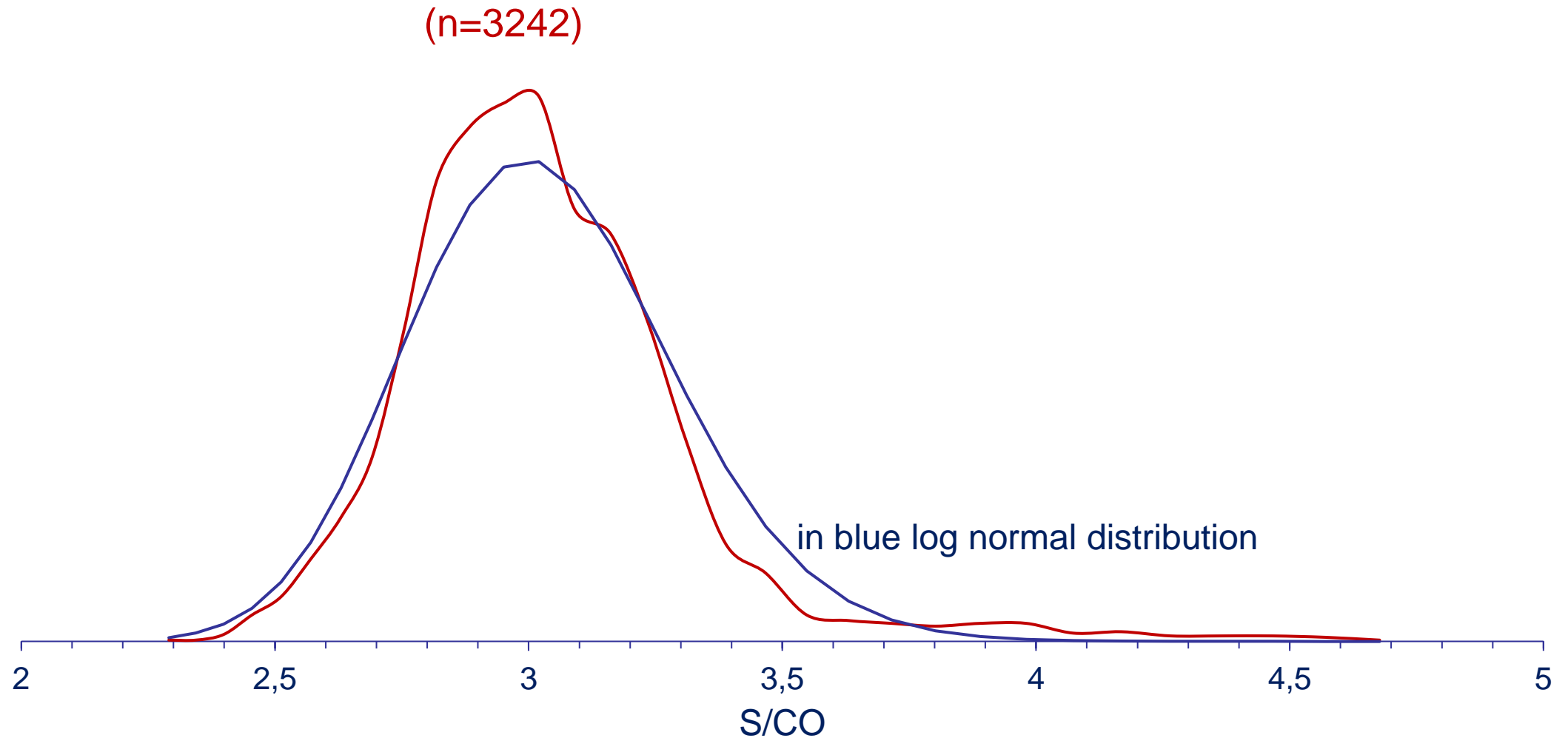
Consistency of P0273 ViraQ Check 75 in cobas MPX

Reagent lot	Average HIV-1 RNA Ct (Stdev/n) on ViraQ batches				
	B4264-003	B4264-004	B4264-005	B4264-006	B4264-007
E08514	33,98 (0,30/50)				
E16887	34,11 (0,36/93)				
E24868	34,10 (0,30/50)				
E29921	34,05 (0,32/81)				
E31293	34,04 (0,37/20)				
E31294	34,24 (0,40/75)				
E31351	33,95 (0,33/56)				
F23147	34,17 (0,36/90)	34,05 (0,46/7)			
G15705	34,46 (0,34/91)	34,35 (0,32/86)	34,39 (0,39/39)		
G30218	34,36 (0,46/55)	34,24 (0,29/71)			
H09363		34,36 (0,37/45)	34,37 (0,33/48)	34,11 (0,29/26)	34,12 (0,40/55)
H14558			34,14 (0,36/131)	34,10 (0,38/12)	
H28856			34,15 (0,28/5)		
H29158				34,24 (0,32/57)	
H33238			34,07 (0,16/3)	34,21 (0,31/19)	

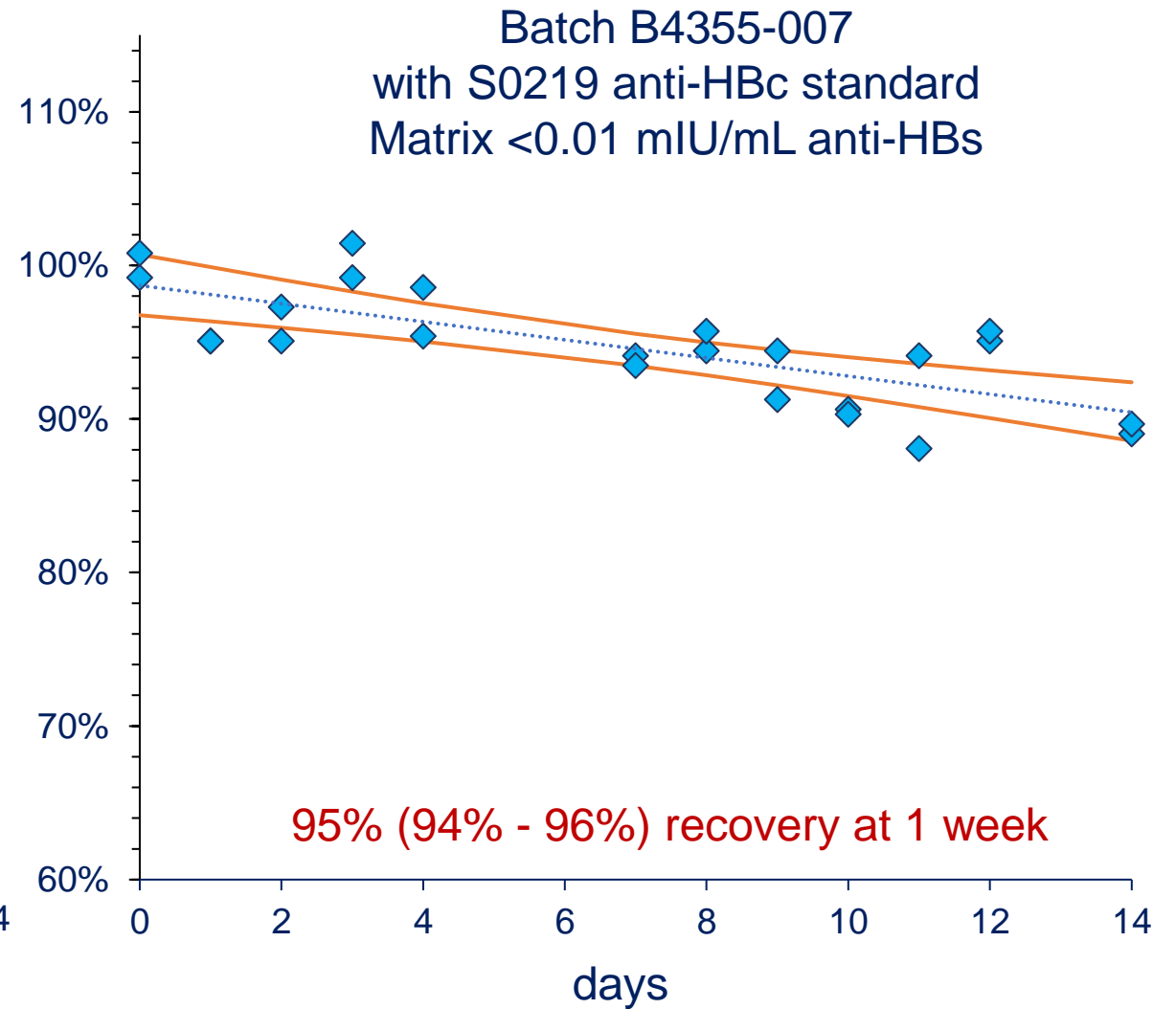
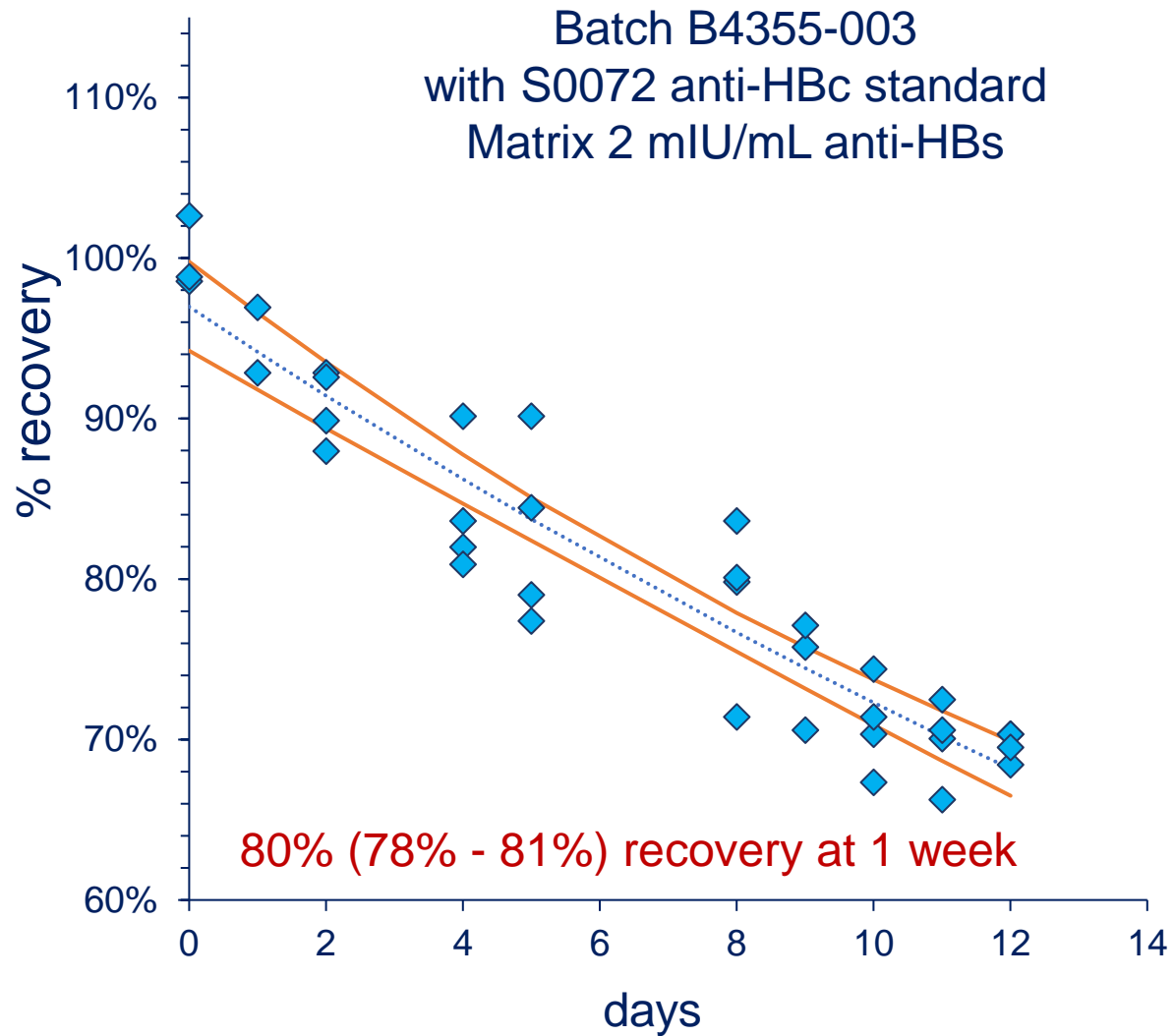
Abbott Alinity HBsAg S/CO values on standard dilutions



HBsAg Alinity S/CO distribution



HBsAg stability in P0386 SeraQ Alinity V4 run control at 2-8°C



Scope DataQ Analytics

We strive to provide all QC for microbiological testing in blood banks

- SeraQ Controls - ready
- ViraQ Controls - ready in Q2 2023
- EQAS panels
- Standard dilution panels
- Multiple genotype panels

DataQ Analytics is integrated in ERP system

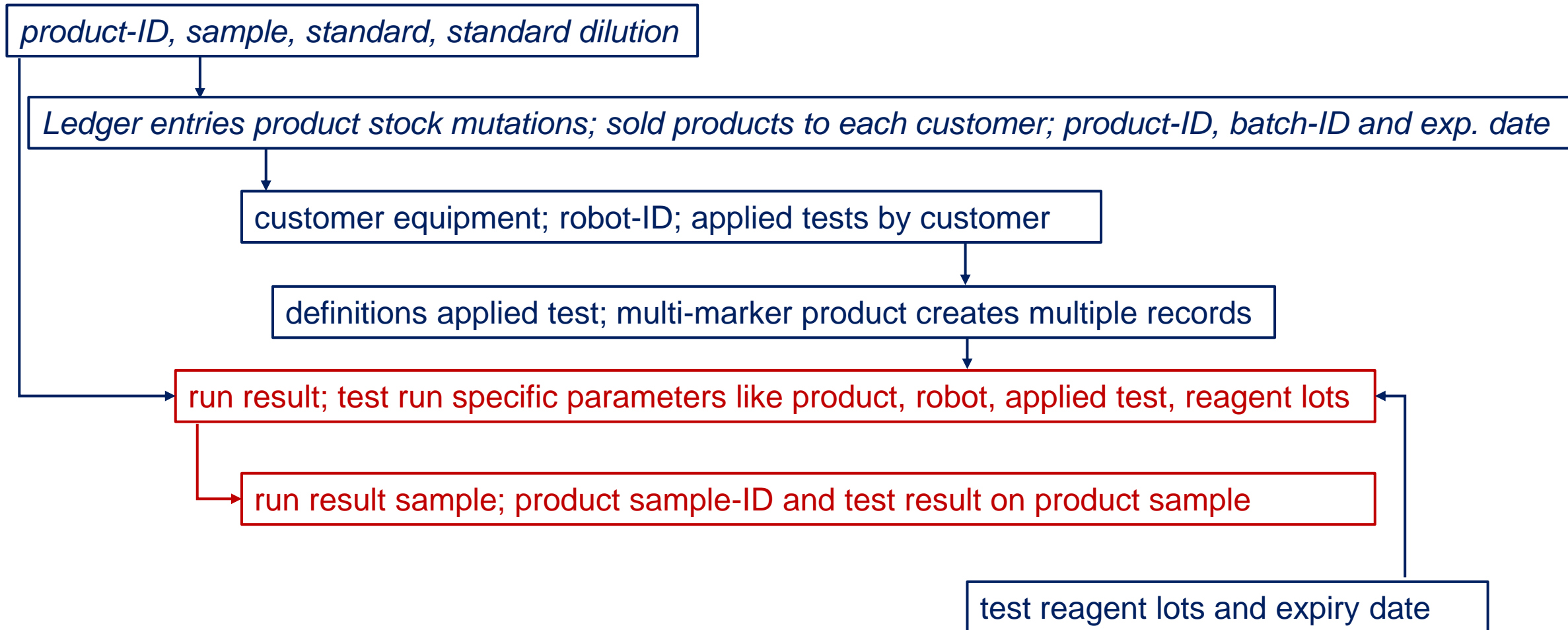
Standard version includes:

- Finance
- Purchasing
- Full warehouse management (including batch registration)
- Manufacturing
- Sales
- Customer Relation Management
- Human Resources

Add on:

- QA registrations (document control and CAPA)
- DataQ Analytics  **Web application**

Core of the DataQ relational database



In italic = in standard package, other tables are defined for DataQ
in red tables used for reporting

DataQ for run controls post market performance follow-up

Limited effort for maximised output

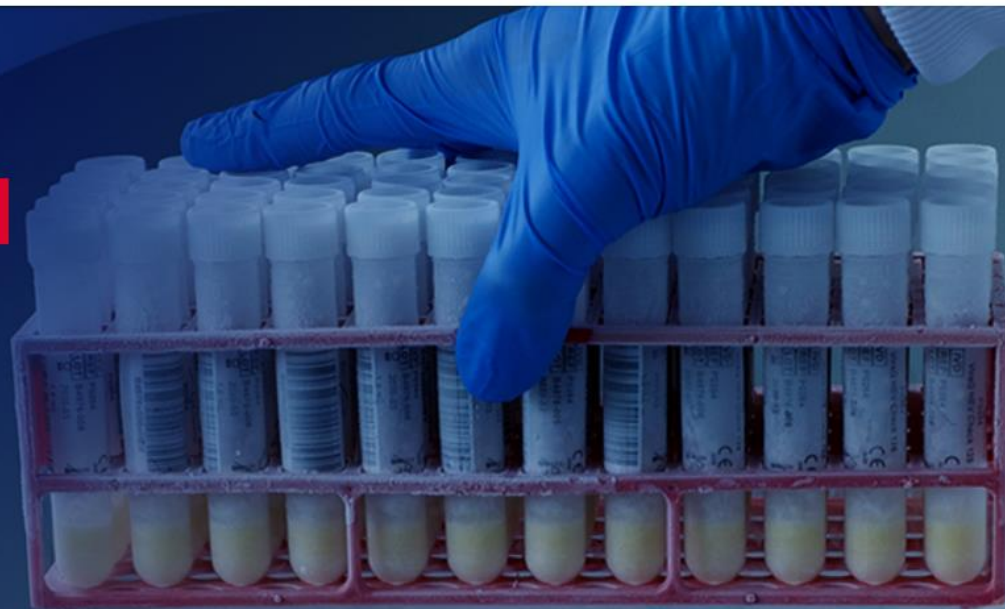
- Collection of analytical sensitivity, robustness and specificity results
- Assay specific data entry screens
- Assay specific statistical reports

To DataQ Analytics on BioQControl.com



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YOUR PARTNER IN QUALITY CONTROL

BioQCControl provides consistent validation and quality control products for infectious disease tests. For more than two decades our reference panels and run controls have been used to evaluate blood safety testing internationally.

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Bio **QC**Control

CREATING CONFIDENCE



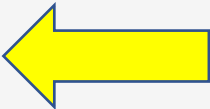
DataQ Analytics

Please sign in

E-mail

Password

Two factor authentication method



DataQ Analytics – Start Page – Lab Profile

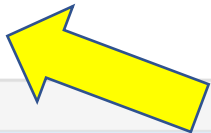
Lab Profile

Customer: (K00170) - nico.lelie@bioqcontrol.com

DataQ Result Entry - SeraQ Controls

Serology Lab Equipment

SeraQ Products



DataQ Analysis & Statistics - SeraQ Controls

SeraQ Reports

DataQ Result Entry - ViraQ Controls

NAT Lab Equipment

ViraQ Products

DataQ Analysis & Statistics - ViraQ Controls

ViraQ Reports

Select purchased SeraQ product and marker

Lab Profile / SeraQ Products

Customer: Sanquin National Screening Service (K00170) - nico.llelie@bioqcontrol.com

P0316 SeraQ Alinity V1



P0320 SeraQ Alinity V2



P0374 SeraQ Alinity V3



P0386 SeraQ Alinity V4



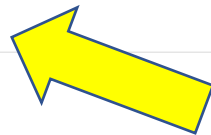
Anti-HBc

Anti-HCV

Anti-HIV-1/2

Anti-HTLV-1/2

HBsAg



Lab Profile / SeraQ Products / SeraQ Results

Customer: Sanquin National Screening Service (K00170) - nico.lielie@bioqcontrol.com

Assay: Alinity s HBsAg Reagent

Product: P0386 SeraQ Alinity V4

Marker: HBsAg

Reagent Lot Test Results Specificity

Result entry by day Result entry by week

Alinity S instruments

Day	Date	Run		AS1037	AS1051	AS1052	AS1053	AS1054	AS1210	
	Sun	02-04	1	Lot nr. test reagent	44584FN00	44584FN00	44584FN00	44584FN00	44584FN00	44584FN00
					New lot nr. +	New lot nr. +	New lot nr. +	New lot nr. +	New lot nr. +	
				Batch-ID run control	B4355-007	B4355-007	B4355-007	B4355-007	B4355-007	B4355-007
				S/CO ratio						
				Comment						
				Samples tested						
				Samples Invalid						
				Initial reactive						
				Repeat reactive						
				Confirmed positive						

SeraQ result entry
(Alinity HBsAg assay)

SeraQ result entry (lotnumber selection Alinity HBsAg assay)

Reagent Lot Test Results Specificity

Result entry by day Result entry by week

Day	Date	Run	AS1037	AS1051	AS1052	AS10		
Save results	Sun	02-04	1	Lot nr. test reagent	44584FN00	44584FN00	44584FN00	44584FN00
				Batch-ID run control	39267FN00 41014FN00 42658FN00 44584FN00	New lot nr.	New lot nr.	
				S/CO ratio		B4355-007	B4355-007	
				Comment				

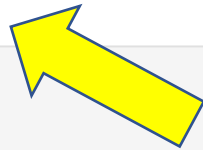
Select purchased ViraQ product

Lab Profile / ViraQ Products

Customer: Sanquin National Screening Service (K00170) - nico.lelie@bioqcontrol.com

P0264 ViraQ HEV Check 125

P0273 ViraQ Multi-Marker Check 75



Lab Profile / ViraQ Products / Roche Results

Customer: Sanquin National Screening Service (K00170) - nico.lelie@bioqcontrol.com

Product: P0273 ViraQ Multi-Marker Check 75

Markers: HBV-DNA, HCV-RNA, HIV-1-RNA

Reagent Lot Test Results **Specificity**

cobas 8800 instruments

Result entry by day Result entry by week

Day Date Run

A

B

Save results

Discard changes

Tue 02-05 1

Lot nr. test reagent

H14558

New lot nr. +

Batch-ID run control

B4264-006

New lot nr. +

B4264-003

HIV-1-RNA HBV-DNA HCV-RNA IC

Ct value

34.2

34.1

36.4

37.0

HIV-1-RNA HBV-DNA HCV-RNA IC

34.1

34.2

36.4

37.0

Comment

Samples tested

Samples Invalid

Initial reactive

Repeat reactive

Confirmed positive

**ViraQ result entry
(cobas MPX assay)**

Previous day

02-04

...

29-04

30-04

01-05

02-05

DataQ result entry per day (cobas MPX)

Reagent Lot Test Results Specificity

Result entry by day Result entry by week



Day	Date	Run	A				B		
Save results	Tue	02-05	1	Lot nr. test reagent	H33238				
					New lot nr.				
Discard changes				Batch-ID run control	B4264-006				
				HIV-1-RNA	HBV-DNA	HCV-RNA	IC	HIV-1-	
				Ct value	34.2	34.1	36.4	37.0	3
				Comment					
				Samples tested					
				Samples Invalid					
				Initial reactive					
				Repeat reactive					
				Confirmed positive					

Previous day 02-04 ... 29-04 30-04 01-05 02-05

DataQ result entry (specificity and robustness parameters cobas MPX)

👁 Reagent Lot 👁 Test Results 👁 **Specificity**

Result entry by day Result entry by week

			Day	Date	Run	A			
<p>Save results </p> <p>Discard changes </p>	Tue	02-05	1		HIV-1-RNA	HBV-DNA	HCV-RNA	IC	
	Samples tested	<input type="text"/>	<input type="text"/>	<input type="text"/>					
	Samples Invalid	<input type="text"/>	<input type="text"/>	<input type="text"/>					
	Initial reactive	<input type="text"/>	<input type="text"/>	<input type="text"/>					
	Repeat reactive	<input type="text"/>	<input type="text"/>	<input type="text"/>					
	Confirmed positive	<input type="text"/>	<input type="text"/>	<input type="text"/>					

DataQ Analytics – Start Page – Lab Profile

Lab Profile


Customer: (K00170) - nico.lelie@bioqcontrol.com

DataQ Result Entry - SeraQ Controls

Serology Lab Equipment

SeraQ Products

DataQ Analysis & Statistics - SeraQ Controls

SeraQ Reports 

DataQ Result Entry - ViraQ Controls

NAT Lab Equipment

ViraQ Products

DataQ Analysis & Statistics - ViraQ Controls

ViraQ Reports

SeraQ statistical report definition (Alinity HBsAg assay)

DataQ Analysis & Statistics - SeraQ Controls

SeraQ Product: P0386

P0386 SERAQ ALINITY V4

Start date:

01-01-2023

End date:

02-05-2023

Marker:

HBsAg

Test Reagent Lot No: (Optional)

All

Search

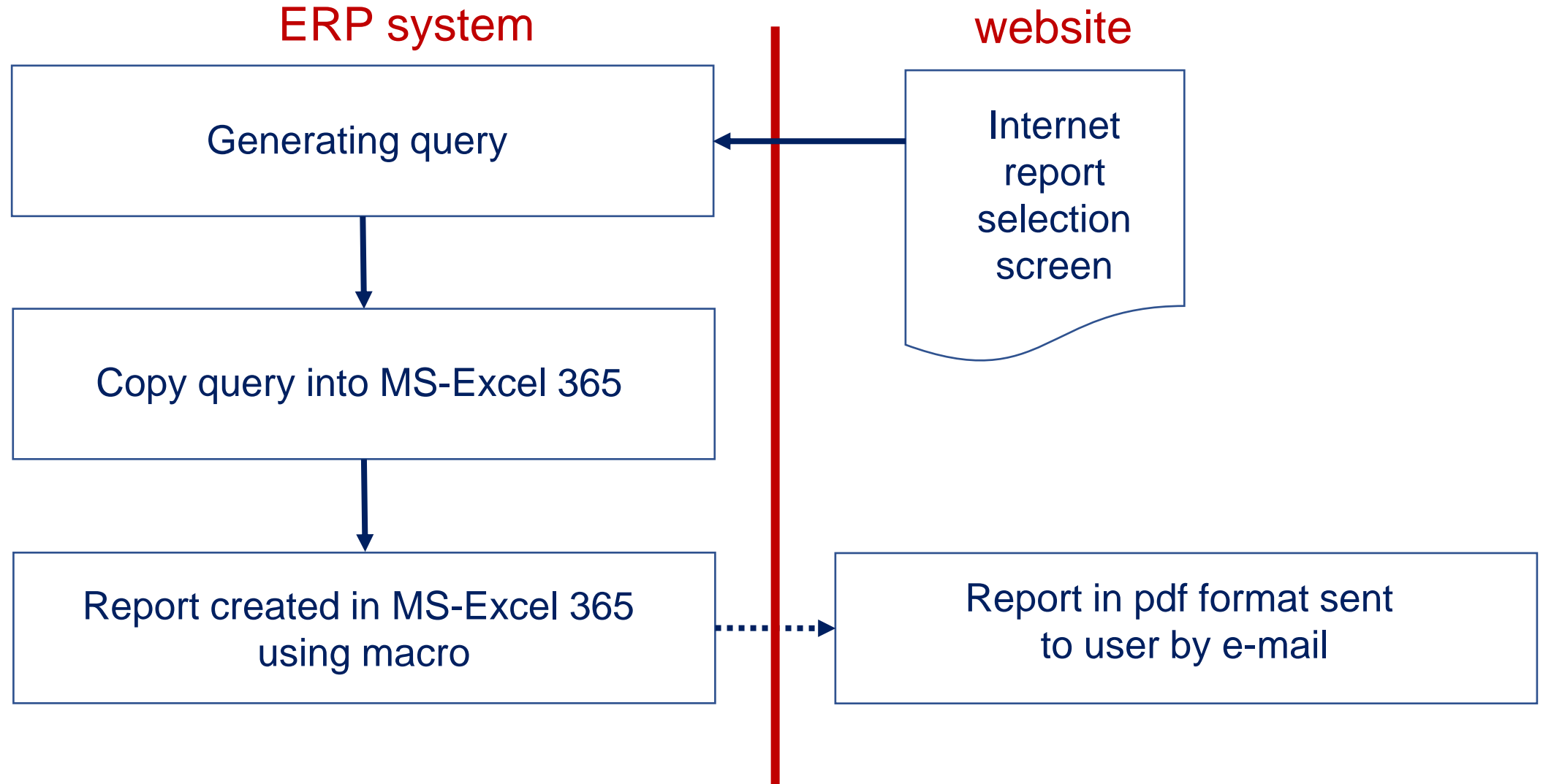
42658FN00

44584FN00

Reagent lot selection option

Generate Statistical Report

DataQ data flow for generating statistical report



DataQ Analytics

Interlaboratory comparison - Statistical Report

Laboratory: Sanquin National Screening Service

Product: P0386 SeraQ Alinity V4

Assay: Alinity s HBsAg Reagent

Manufacturer: Abbott

Marker: HBsAg

Result Unit: S/CO

Report date: 24 04 2023

at 14:46

Summary statistics with intervals based on LogNormal distribution

	n	GeoMean	%CV	95% pred.int.		99% pred.int.	
Peer	1014	3,02	6,408	2,66	3,42	2,56	3,56
Customer	974	3,01	5,248	2,72	3,34	2,63	3,45
All	1988	3,01	5,868	2,69	3,38	2,59	3,51

Start date 01-06-22

End date 18-04-23

Violations of Nelson rules by customer

Rule	n	%	Short description
Nr.1	4	0,4	1 value beyond 99% limit
Nr.5	1	0,1	2 consecutive values beyond same 95% limit
Nr.3	2	0,2	6 consecutive values continuously increasing or decreasing

56 observations with value <0,1 removed

2 observations with value >6 removed

Levey-Jennings chart

