

# Results of external quality control for direct oral anticoagulant testing

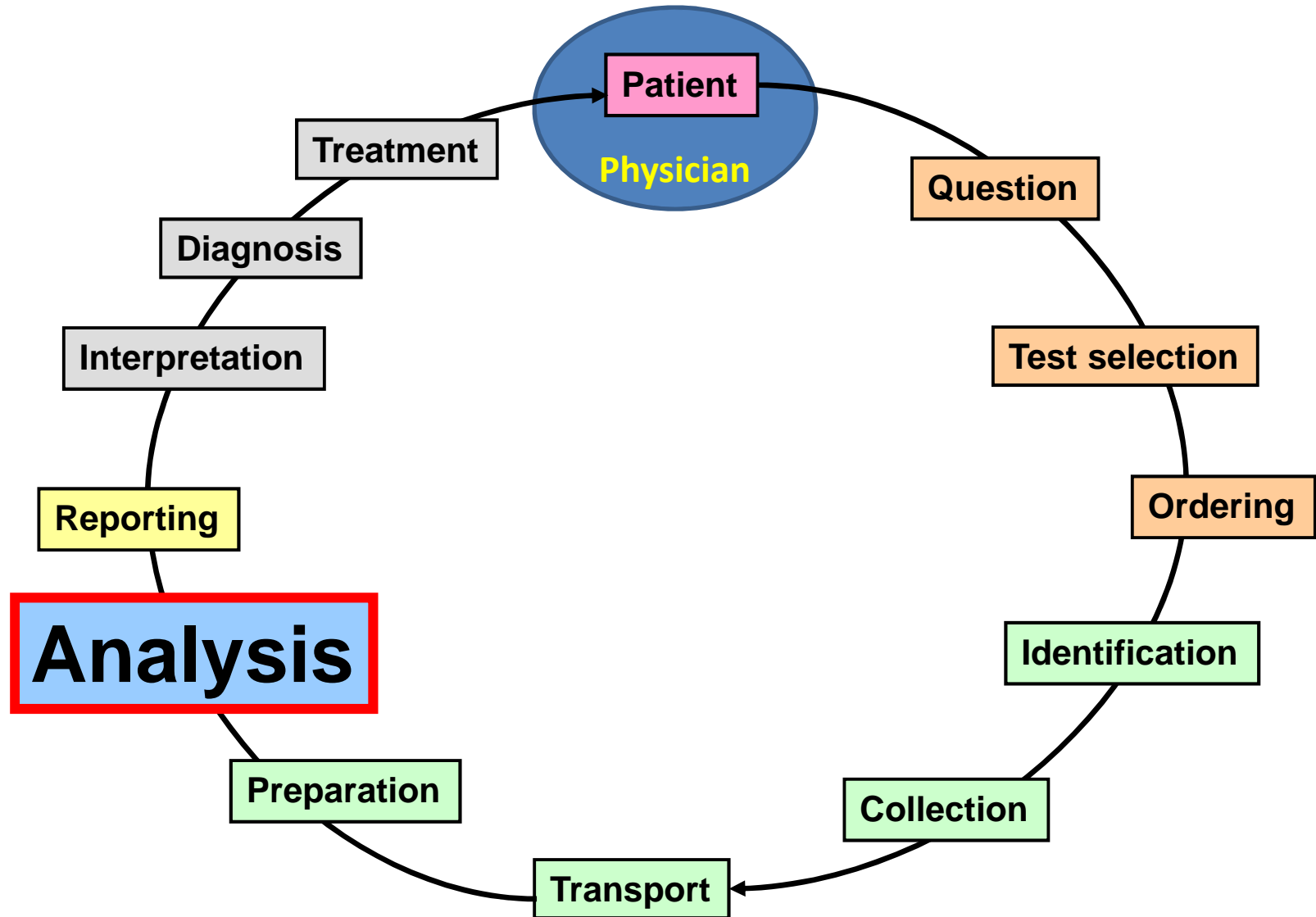
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***“Although the burden of the clinical laboratory accounts for only 7% of the total public healthcare costs, **clinical laboratories play a crucial role (70%) in clinical decisions (admittance, discharge, diagnosis and therapy),*****  
.....”

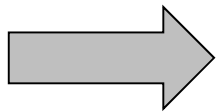


# Total Testing Process



# External Quality Control

**Objective assessment of a participants' performance for the measurement of a particular analyte**



**Deviation from the “true value”**



**Variation between participants**

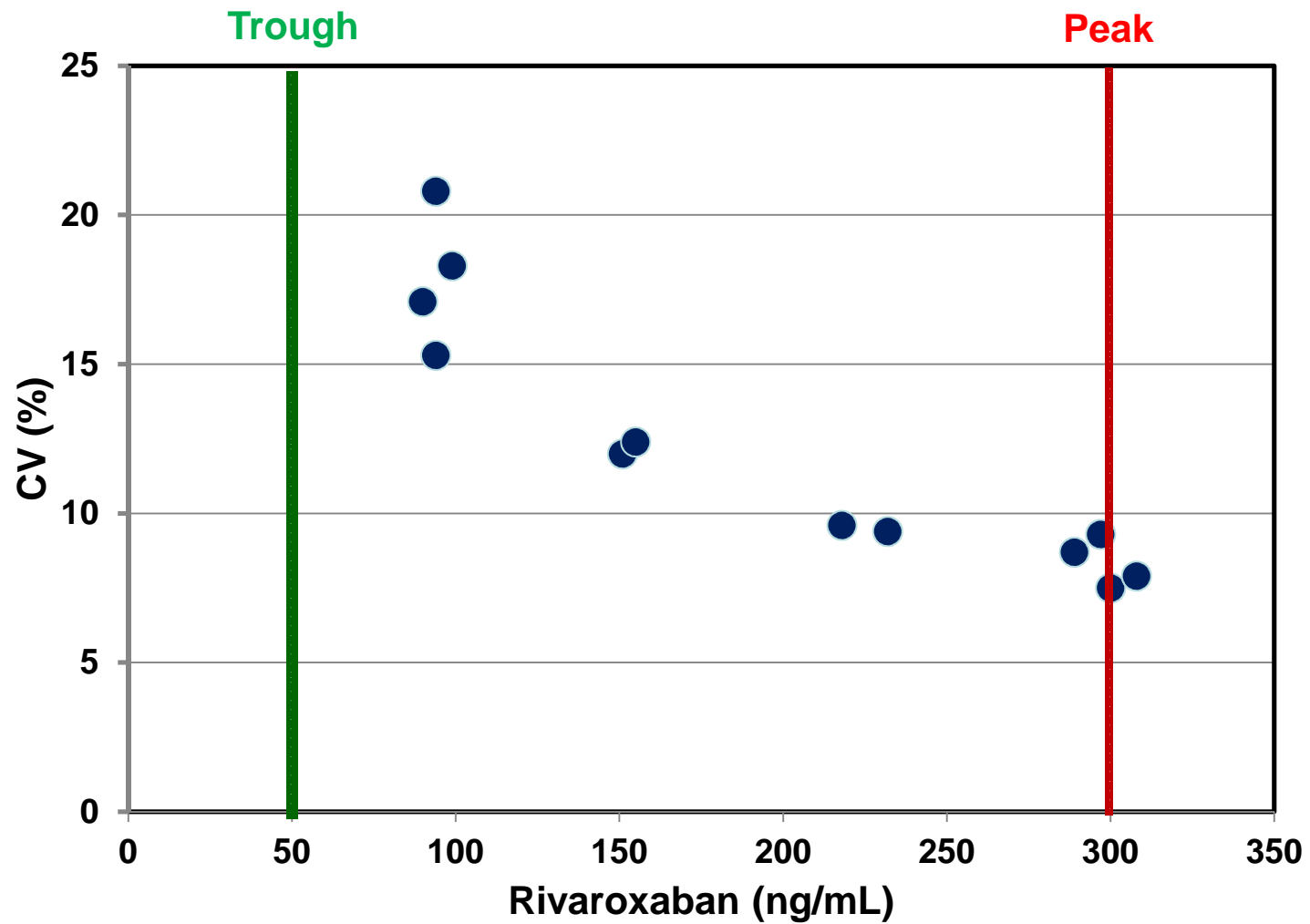


# DOAC's in the ECAT EQA programme

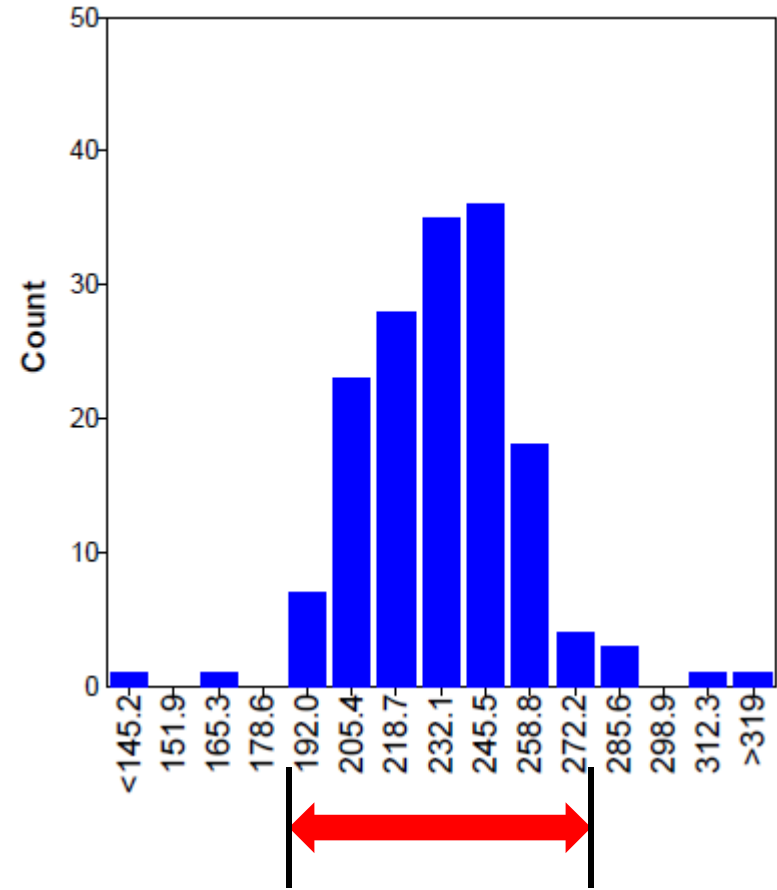
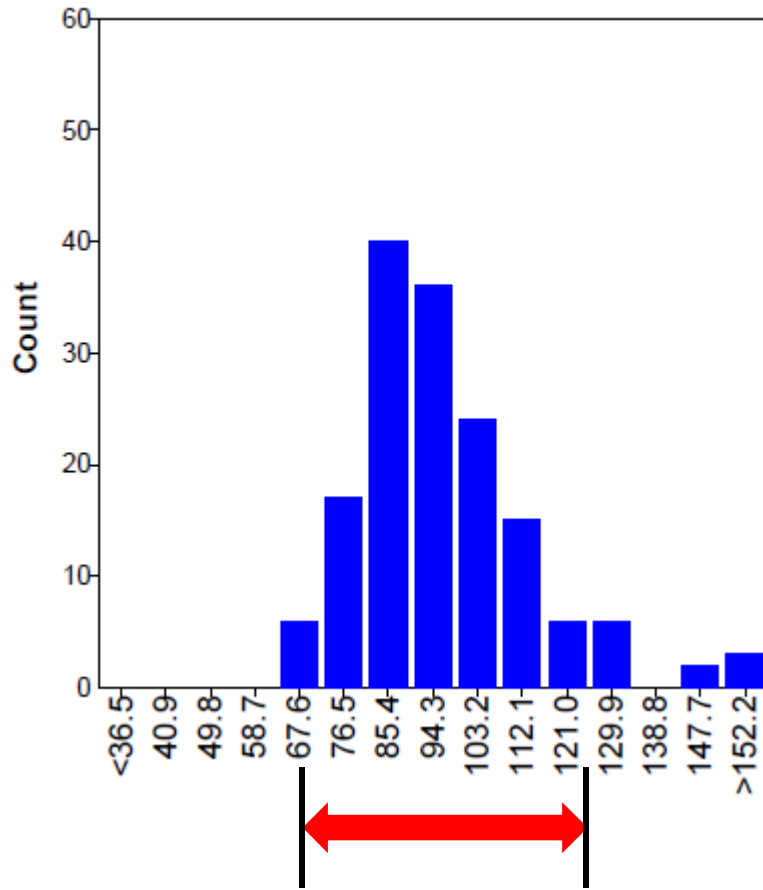
	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>
Rivaroxaban	77	128	178	196	228
Apixaban	--	--	64	123	167
Argatroban	34	35	34	41	45
Dabigatran	87	152	197	177	198



# RIVAROXABAN (ng/mL)



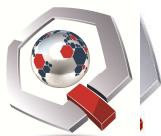
# RIVAROXABAN (ng/mL)



# RIVAROXABAN (ng/mL)

Method	N	155 ng/mL	300 ng/mL
Coamatic Heparin (Chromogenix)	12	150 ± 15	286 ± 21
HemosIL Liquid Heparin (IL)	15	155 ± 14	316 ± 15
Biophen DiXa (Hyphen)	17	168 ± 12	308 ± 19
Biophen Heparin (Hyphen)	45	161 ± 18	311 ± 23
Liquid anti-Xa (Stago)	56	147 ± 16	311 ± 24

(mean ± sd)





# RIVAROXABAN (ng/mL)

Calibrator	N	155 ng/mL	300 ng/mL
Hyphen Biomed	102	158 ± 19	309 ± 26
Stago	44	151 ± 23	311 ± 22
<b>P-value</b>		<b>0.07</b>	<b>0.68</b>



# RIVAROXABAN (ng/mL)

Method	Hyphen calibrator		Stago calibrator	
	N	Mean $\pm$ SD	N	Mean $\pm$ SD
Coamatic Heparin (Chromogenix)	9	151 $\pm$ 12	-	-
HemosIL Liquid Heparin (IL)	13	156 $\pm$ 14	-	-
Biophen DiXa (Hyphen)	17	167 $\pm$ 14 *	-	-
Biophen Heparin (Hyphen)	45	159 $\pm$ 22	-	-
Liquid anti-Xa (Stago)	14	145 $\pm$ 19 * / **	17	151 $\pm$ 23 **

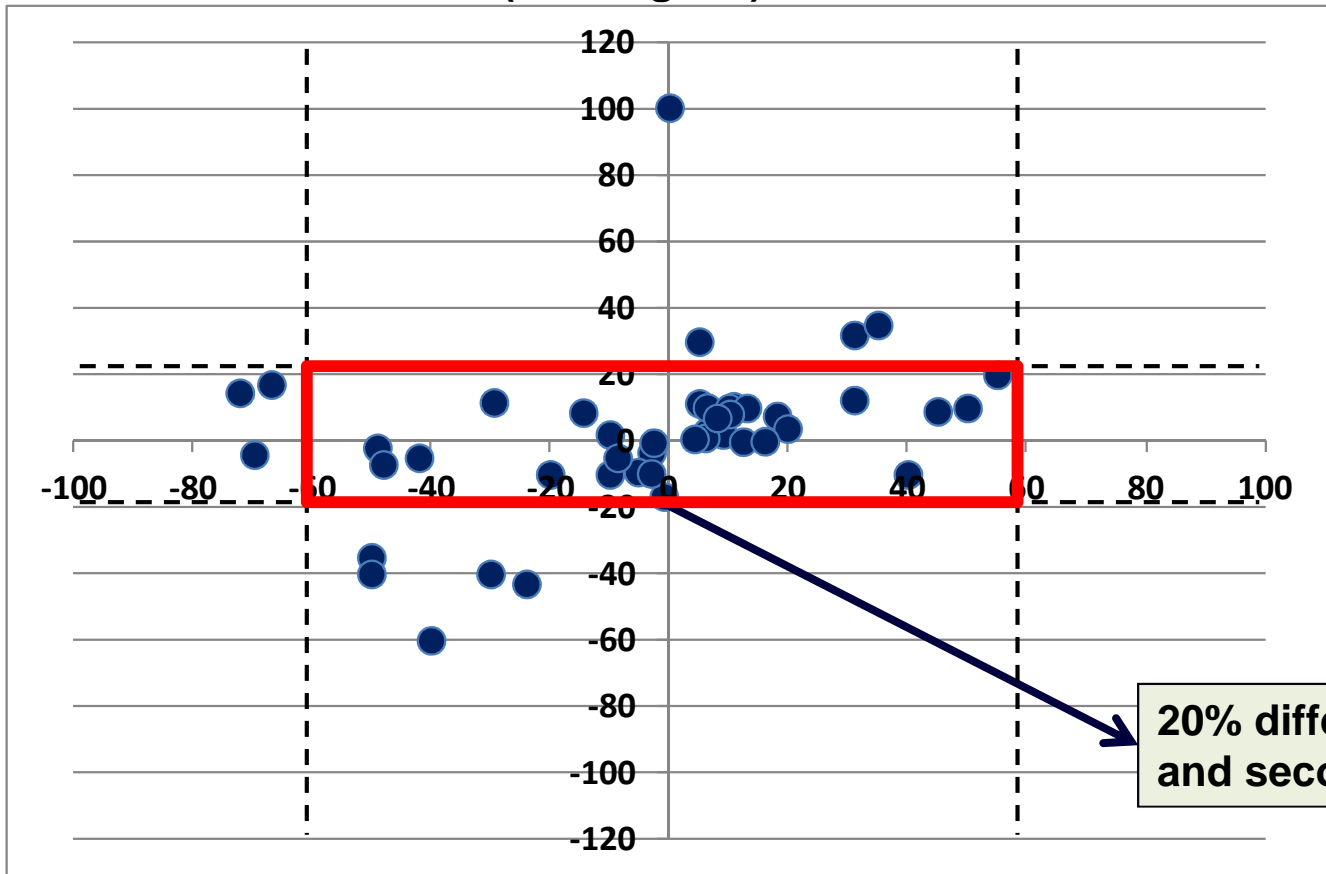
\* P = 0.001

\*\* NS



# RIVAROXABAN (ng/mL)

**Low sample (Y)**  
(~ 100ng/mL)



**High sample (X)**  
(~ 300 ng/mL)



# APIXABAN (ng/mL)

Method	N	140 ng/mL	200 ng/mL	250 ng/mL	400 ng/mL
All	105	139 (9.4)	195 (9.2)	246 (7.6)	406 (9.6)
Coamatic Heparin (Chromogenix)	13	145 (11.3)	199 (9.2)	252 (11.9)	428 (9.8)
Biophen Heparin (Hyphen)	18	141 (9.2)	201 (14.6)	247 (9.2)	398 (18.2)
Liquid anti-Xa (IL)	13	138 (9.1)	197 (7.8)	251 (7.5)	422 (9.5)
Liquid anti-Xa (Stago)	44	136 (7.0)	190 (6.2)	242 (5.7)	400 (4.5)

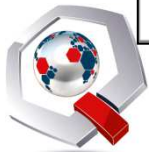
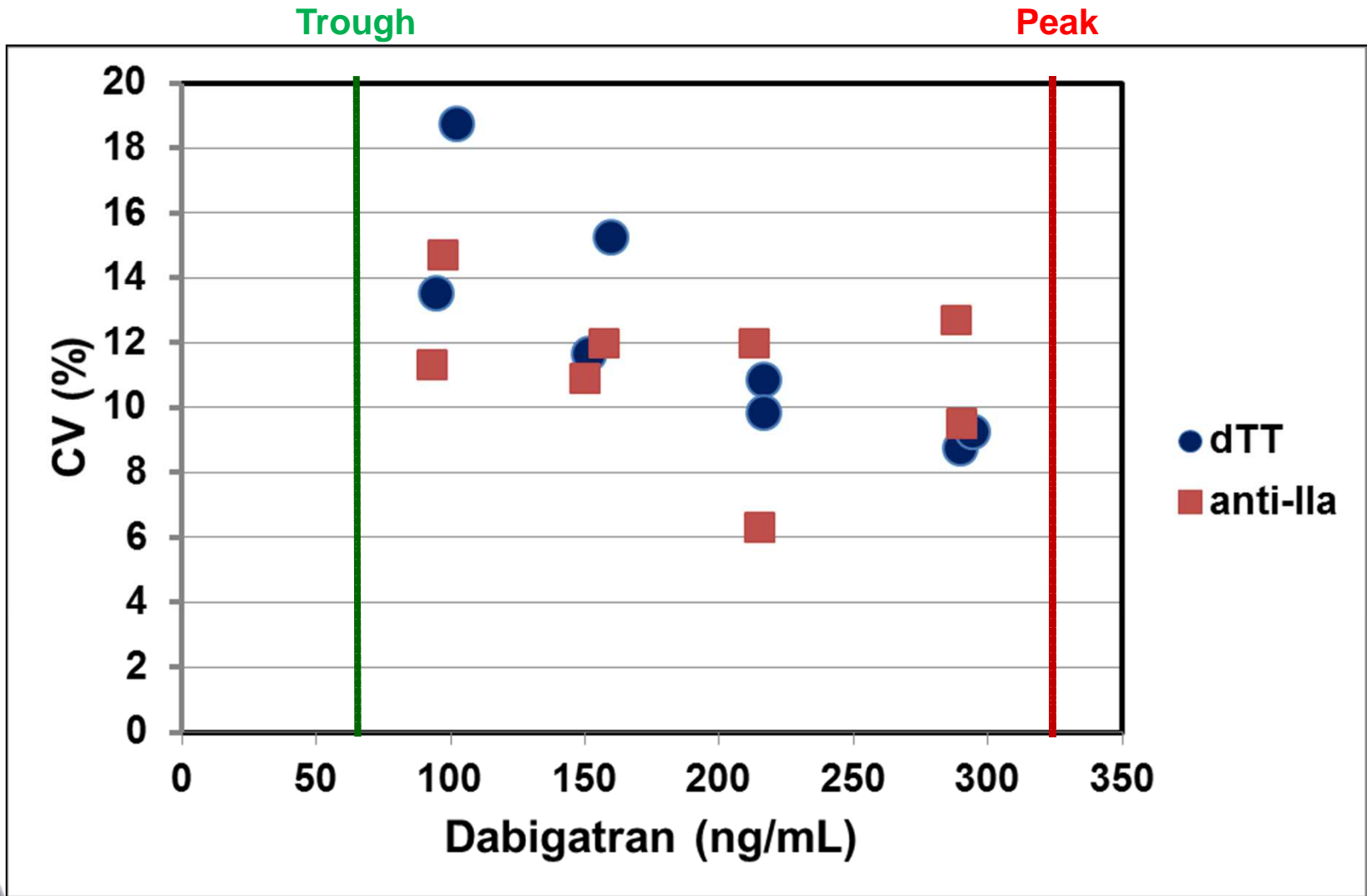


# ARGATROBAN ( $\mu\text{g}/\text{mL}$ )

Argatroban ( $\mu\text{g}/\text{mL}$ )	Anti-IIa			dTT		
	N	Mean	CV (%)	N	Mean	CV (%)
$\pm 0.30 \mu\text{g}/\text{mL}$	16	0.30	17.4	10	0.30	25.9
$\pm 0.50 \mu\text{g}/\text{mL}$	12	0.53	12.4	11	0.55	10.7
	13	0.50	12.6	16	0.52	15.6
$\pm 0.80 \mu\text{g}/\text{mL}$	12	0.82	9.1	11	0.86	8.8
$\pm 0.95 \mu\text{g}/\text{mL}$	13	0.93	13.7	16	0.96	11.0
$\pm 1.10 \mu\text{g}/\text{mL}$	16	1.12	8.0	10	1.09	10.7

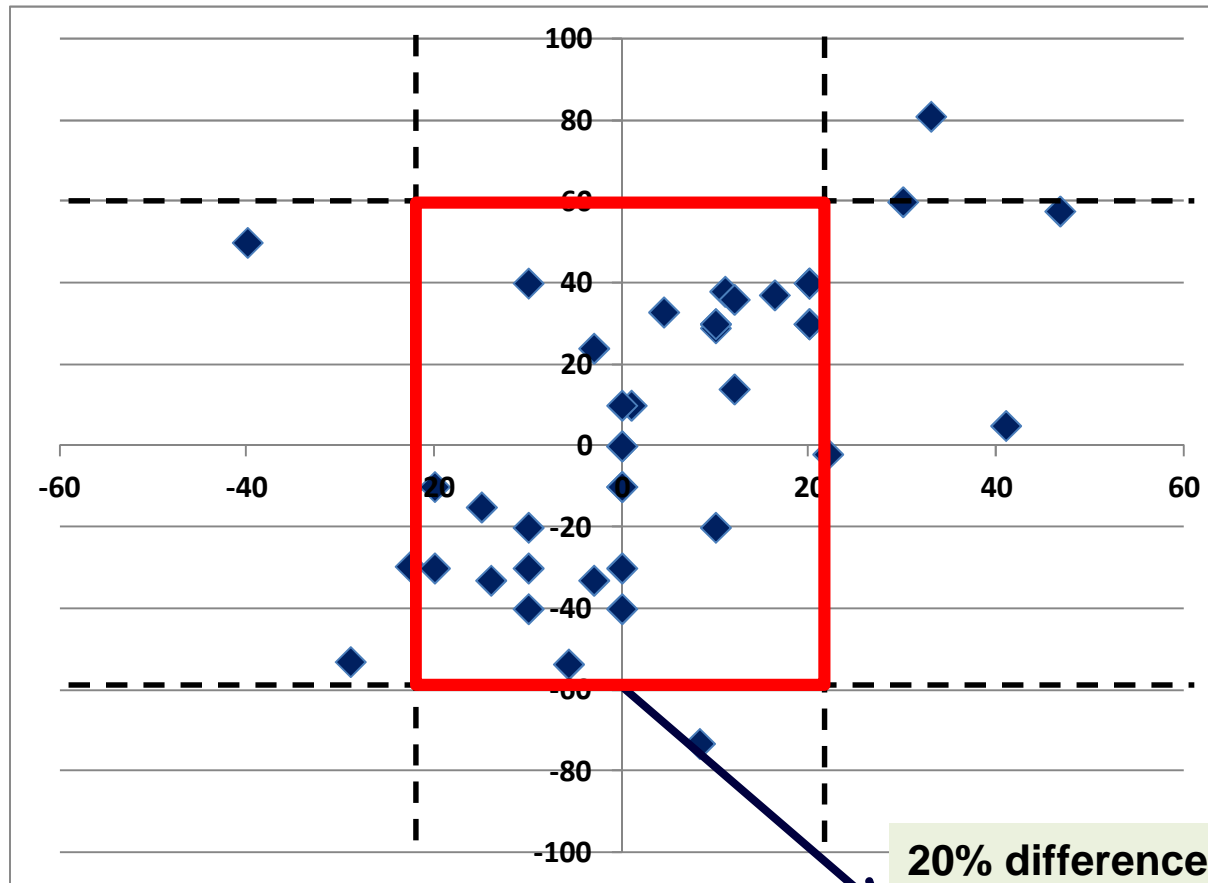


# DABIGATRAN (ng/mL)



# DABIGATRAN (ng/mL)

High sample  
(~300 ng/mL)



Low sample  
(~ 125 ng/mL)

20% difference between first and second measurement



# SUMMARY

Parameter	N	CV between (%)
Orgaran	54 – 90	8 – 16
Fondaparinux	70 – 90	10 – 19
Rivaroxaban	77 – 178	8 – 21
Apixaban	64	7 – 14
Argatroban	34 – 35	9 – 26
Dabigatran	87 – 197	6 - 19





# CONCLUSIONS

- For low concentrations of DOACs there is a considerable variation in test results between laboratories.
- Some laboratories have a considerable variation in the measurement of the same sample over time.
- In general further improvement of the comparability of test results between laboratories and the repeatability of test results within laboratories is necessary.



# Thanks to participants from all over the world

