

ECAT survey results on direct oral anticoagulant testing.

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ECAT FOUNDATION
External quality Control of diagnostic Assays and Tests
with a focus on Thrombosis and Haemostasis

DOAC survey results
9th ECAT Meeting

DOAC's are part of the regular ECAT EQA programme since 2012

	<u>2012</u>	<u>2013</u>	<u>2014</u>
Orgaran	54	77	90
Fondaparinux	70	81	90
Rivaroxaban	77	128	178
Apixaban	--	--	64
Argatroban	34	35	34
Dabigatran	87	152	197

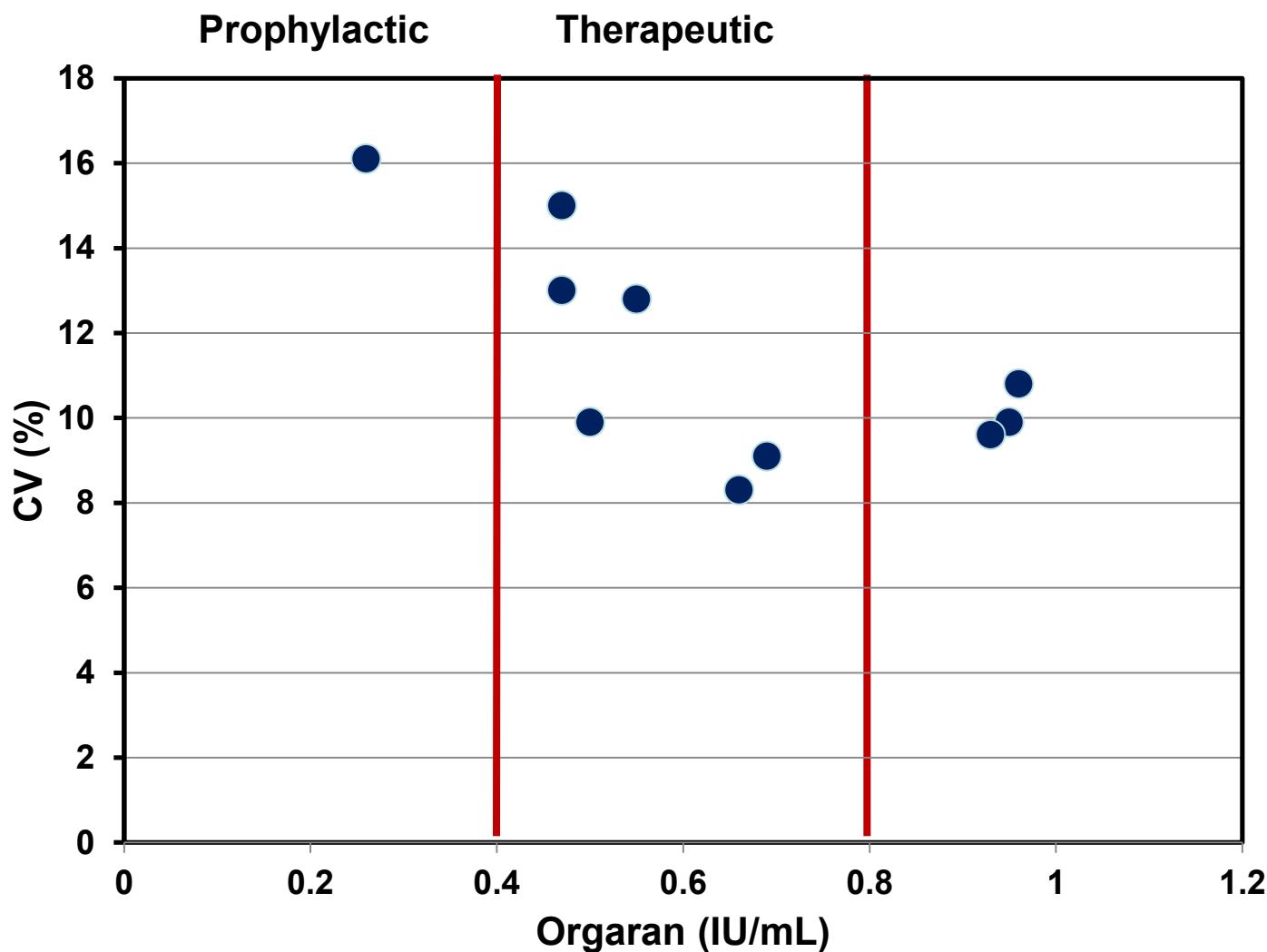


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ORGARAN (IU/mL)



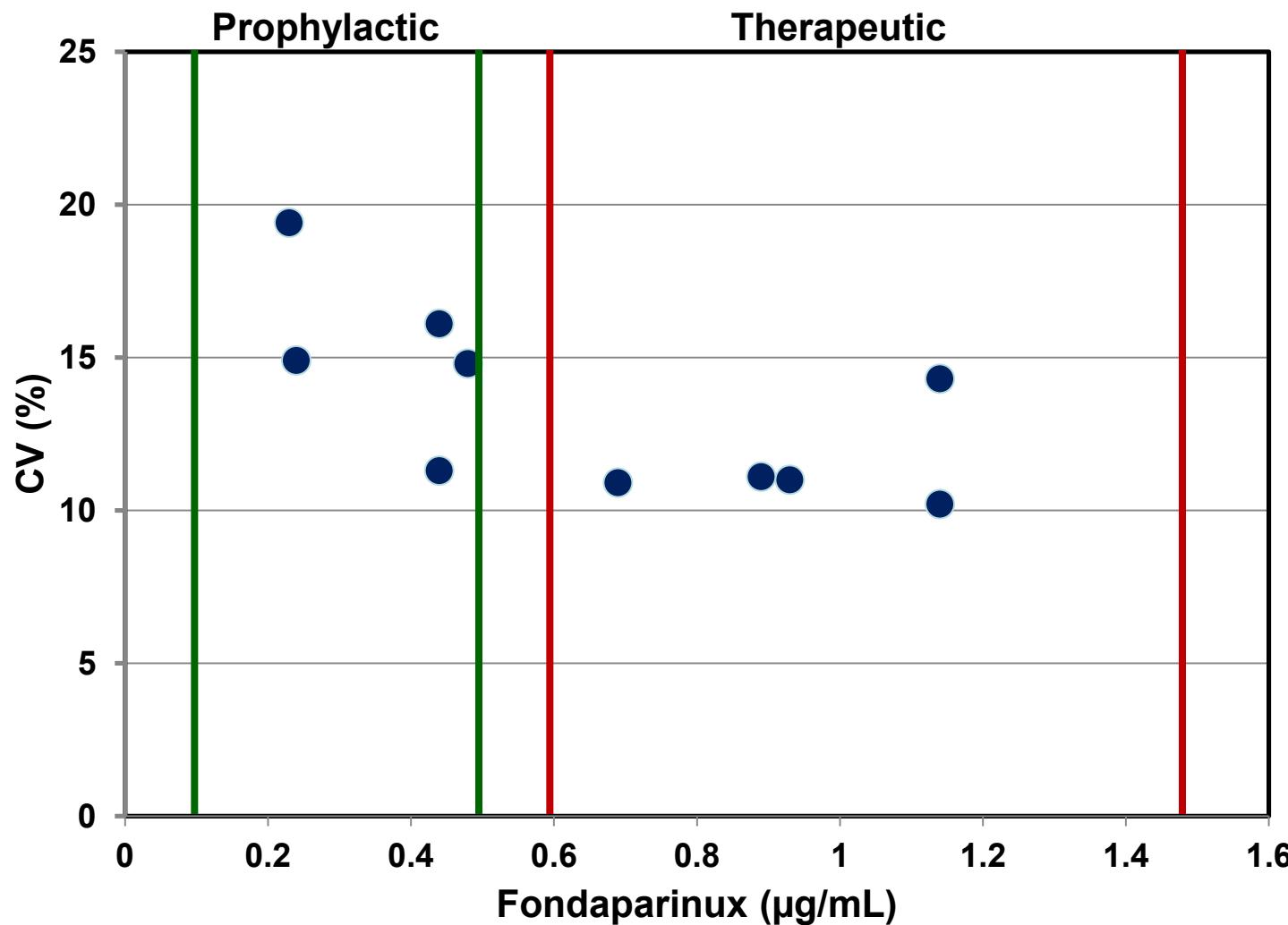
ORGARAN (IU/mL)

Method	N	0.50 IU/mL	0.70 IU/mL
Coamatic Heparin (Chromogenix)	10	0.47 ± 0.04	0.66 ± 0.06
HemosIL Liquid Heparin (IL)	10	0.50 ± 0.05	0.68 ± 0.07
Biophen Heparin (Hyphen)	26	0.52 ± 0.04	0.72 ± 0.05
Liquid anti-Xa (Stago)	34	0.50 ± 0.05	0.69 ± 0.06

(mean ± sd)



FONDAPARINUX ($\mu\text{g/mL}$)



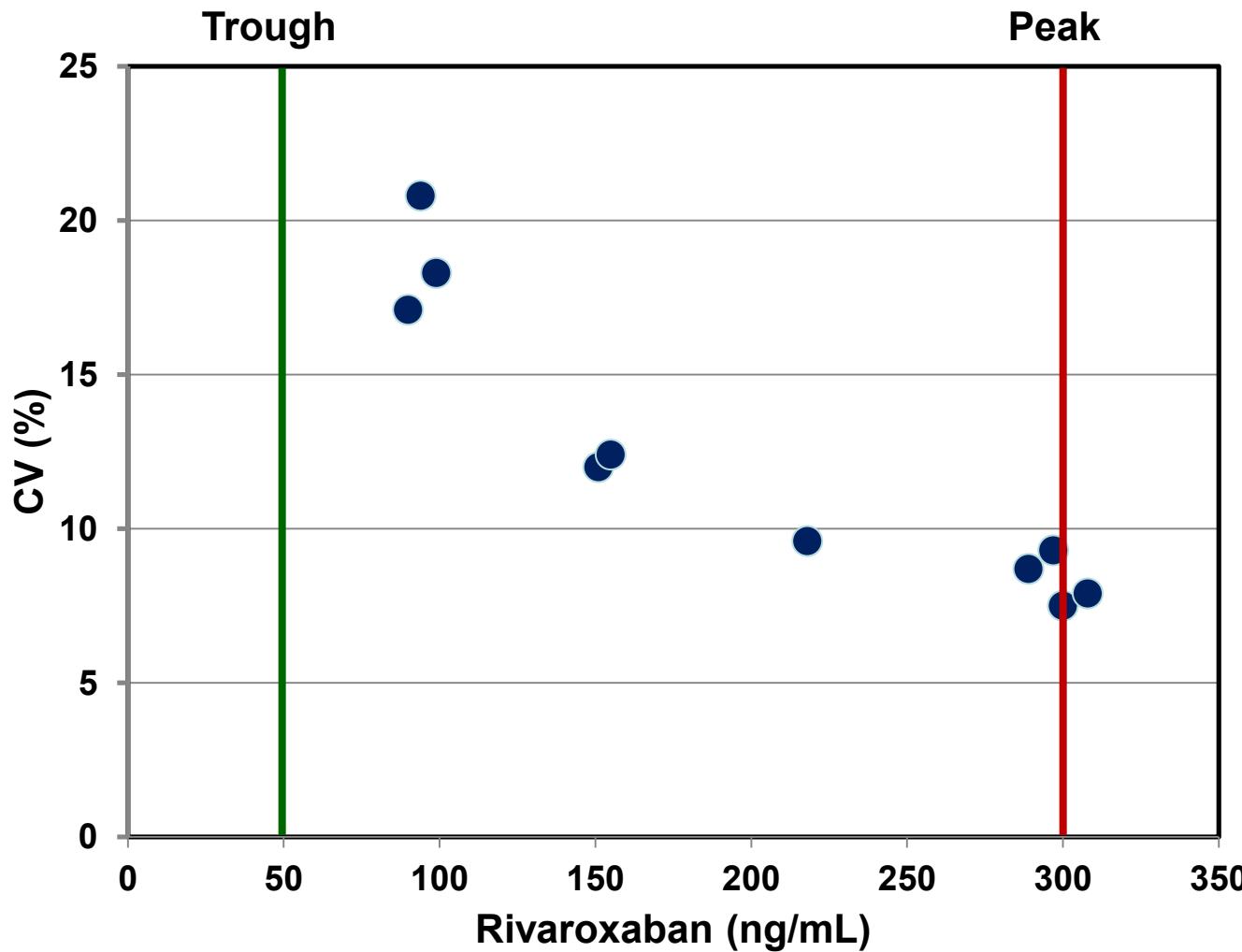
FONDAPARINUX ($\mu\text{g/mL}$)

Method	N	$0.25 \mu\text{g/mL}$	$0.90 \mu\text{g/mL}$
Coamatic Heparin (Chromogenix)	11	0.23 ± 0.03	0.84 ± 0.06
Biophen Heparin (Hyphen)	22	0.27 ± 0.04	0.97 ± 0.07
Liquid anti-Xa (Stago)	28	0.24 ± 0.03	0.88 ± 0.09

(mean \pm sd)



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)



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RIVAROXABAN (ng/mL)

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



RIVAROXABAN (ng/mL)

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

* P = 0.001

** NS



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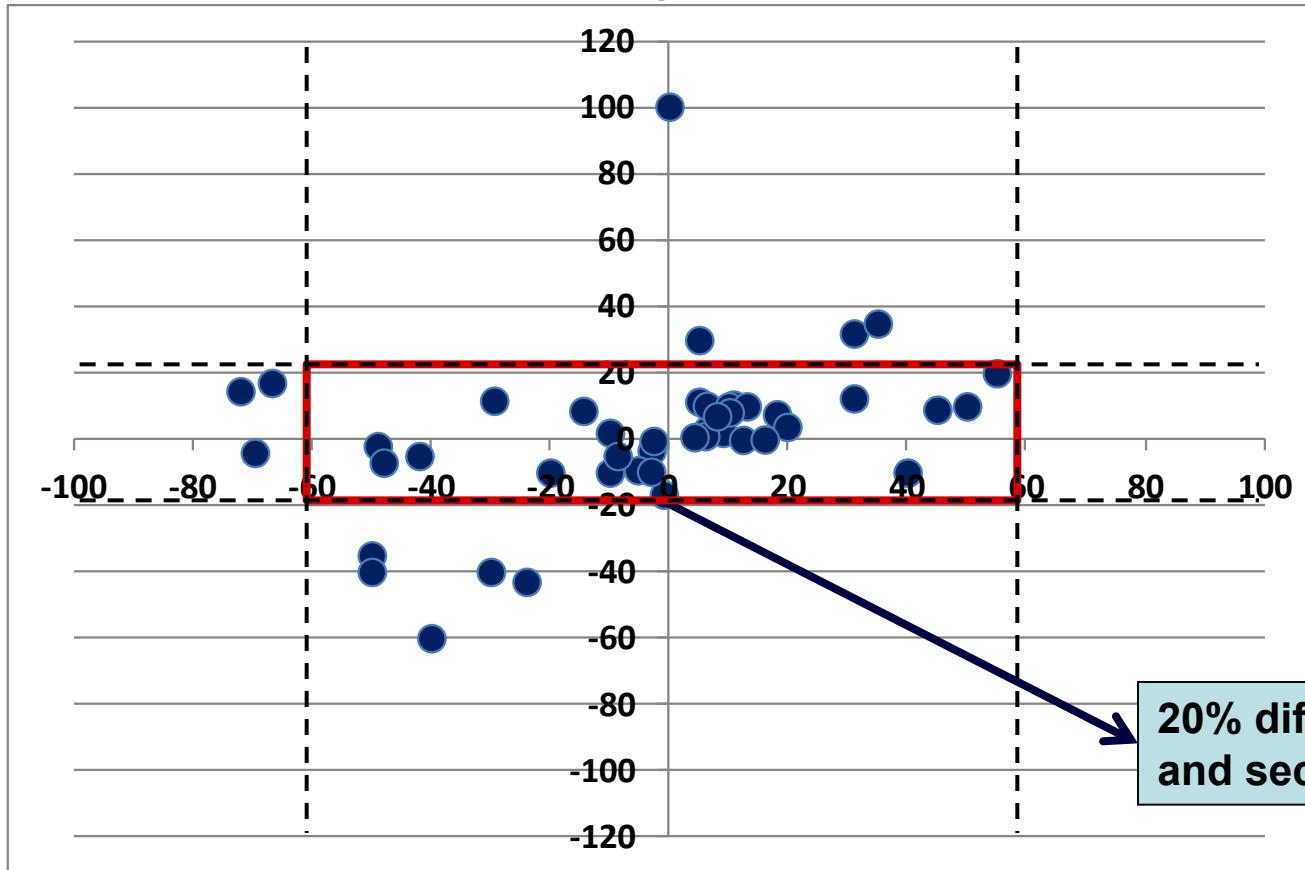
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RIVAROXABAN (ng/mL)

Low sample (Y)

(~ 100ng/mL)



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

20% difference between first
and second measurement



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APIXABAN (ng/mL)

Method	N	65 ng/mL	240 ng/mL
All	41	68 ± 9 (13.9)	241 ± 21 (8.8)
Liquid anti-Xa (Stago)	25	67 ± 6 (8.5)	239 ± 16 (6.9)

(mean \pm sd)



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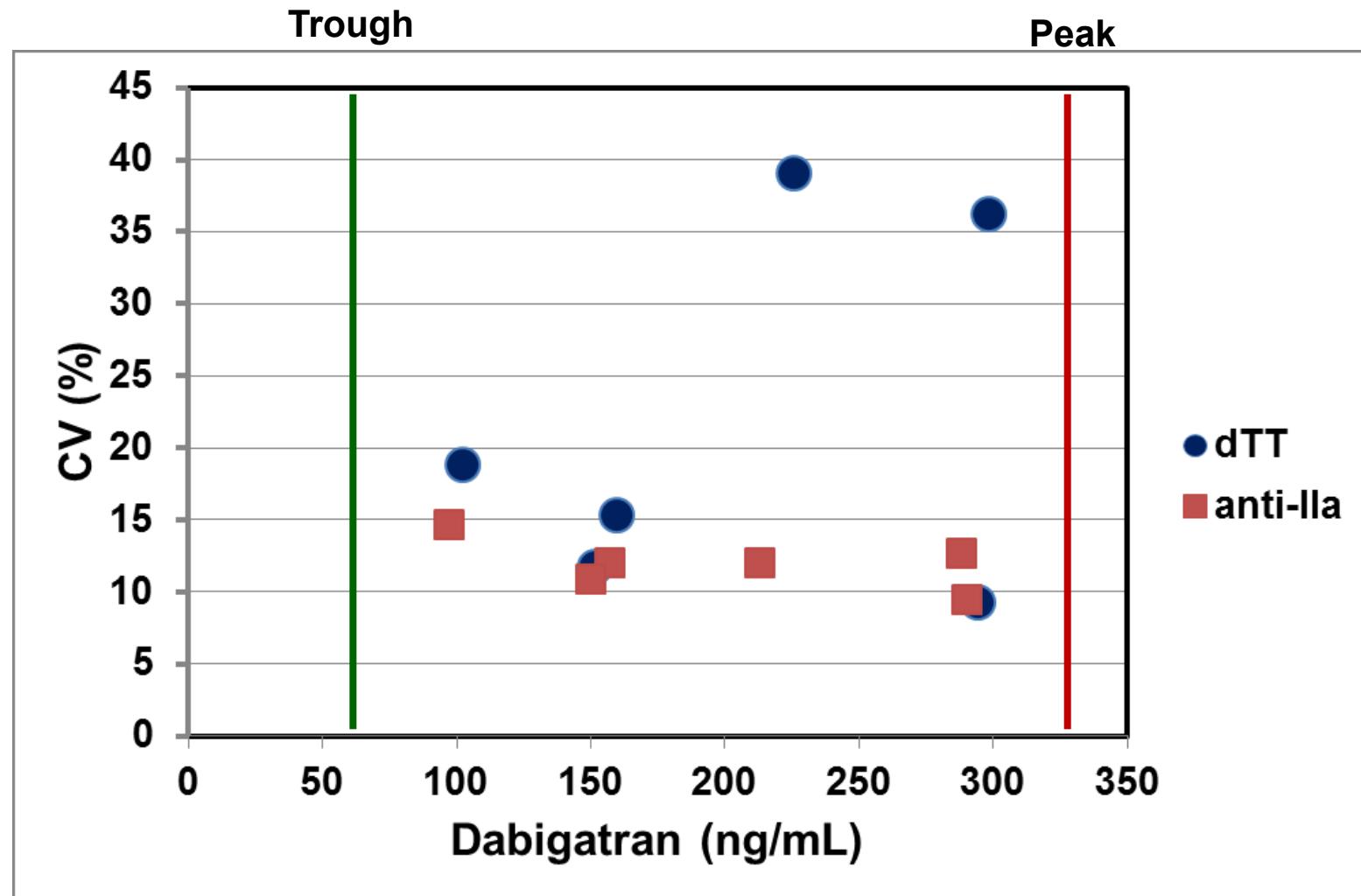
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ARGATROBAN ($\mu\text{g/mL}$)

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



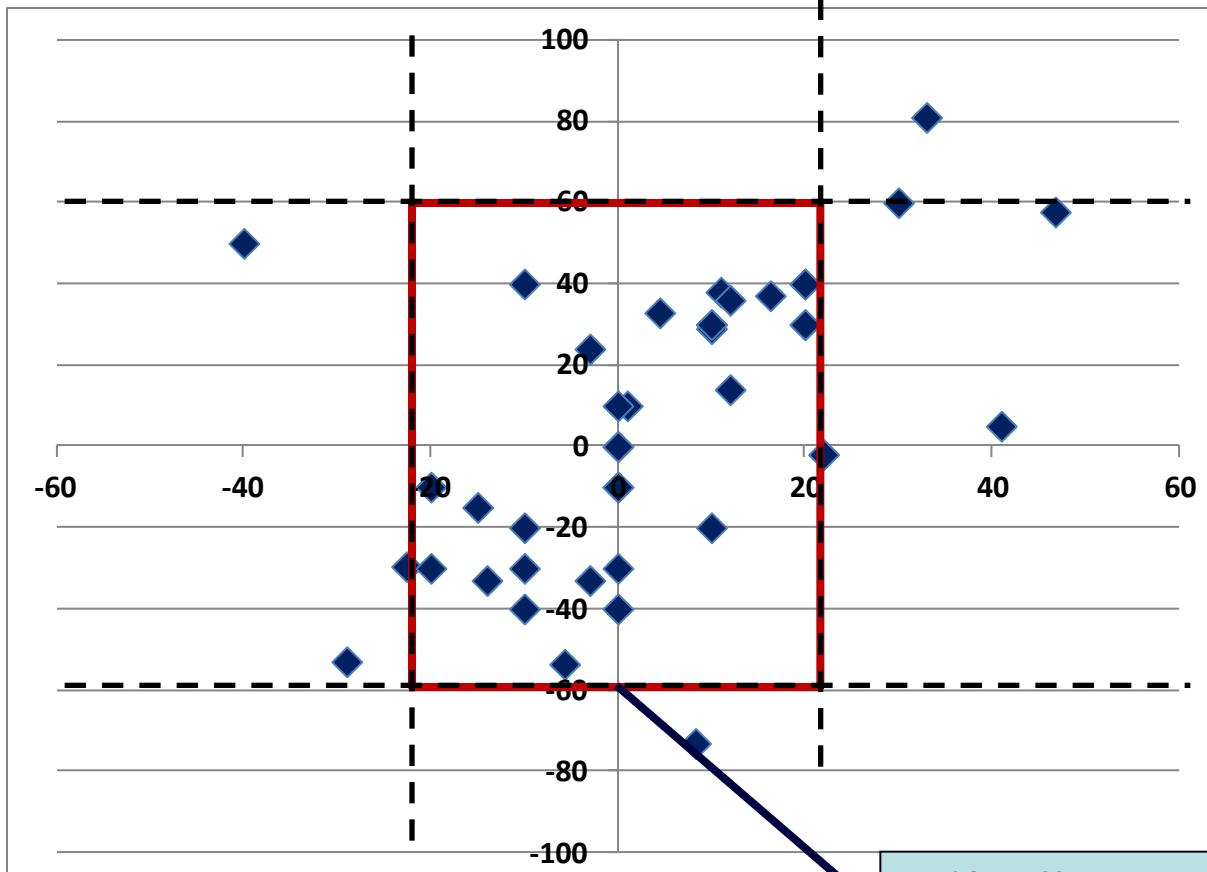
DABIGATRAN (ng/mL)



DABIGATRAN (ng/mL)

High sample (Y)

(~300 ng/mL)



Low sample (X)
(~ 125 ng/mL)

20% difference between first
and second measurement



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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	9 - 19

