

# ADAMTS13

## Results of the ECAT External Quality Assessment Surveys

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# INTRODUCTION

## External Quality Assessment (EQA):

Independent assessment of the quality of performance of an analytical test system.

**Accuracy** : Correct result

**Reproducibility:** Variation between monitors



# INTRODUCTION

## Assessment of the target value

- **No reference methods available.**
- **Target value = consensus value**
- **Robust statistics to minimize effect of outliers**
- **Z-score to assess individual performance**
- **Start with regular surveys in 2014**
- **ADMATS13 activity/antigen: 84 participants**
- **ADAMTS13 inhibitor: 61 participants**



# SURVEY RESULTS



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

**9th ECAT Participants'  
Meeting Leiden nov 2014**

# SAMPLES ADAMTS13 ACTIVITY / ANTIGEN

## Activity / Antigen

Survey 2014-1: approx. **20** and **40** U/dL ADAMTS13 activity

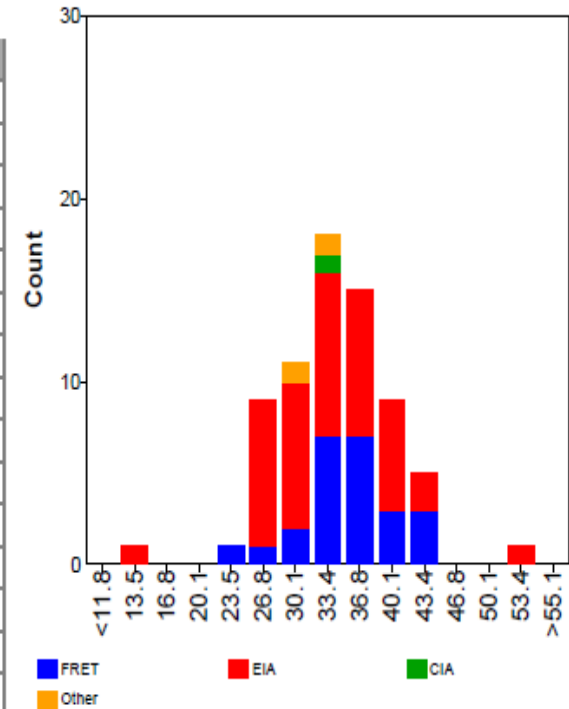
Survey 2014-2: same samples.

Survey 2014-3: approx. **90** and **< 10** U/dL ADAMTS13 activity



# ADAMTS13 ACTIVITY

	n	assigned value	CV (%)	range	your result	z-score
Total Group	70	34	15.3	15 - 55		
FRET	24	36	13.1	23 - 45		
Gen-Probe ADAMTS13 activity	2	39		32 - 45		
Homemade	7	36		28 - 40		
Immucor ADAMTS13 activity	10	36	10.1	23 - 42		
Other	2	37		35 - 38		
Sekisui Actifluor ADAMTS13 activity	3	36		33 - 42		
Enzyme Immuno Assay	43	33	16.2	15 - 55		
DG ADAMTS13 activity	1	33				
Homemade	2	21		15 - 27		
Technoclone Technozym ADAMTS13 aciti	36	33	14.2	26 - 41		
Technoclone Technozym ADAMTS13 activ	4	43		39 - 55		
Chemiluminescence Immuno Assay	1	32				
Homemade	1	32				
Other	2	33		30 - 35		
Homemade	2	33		30 - 35		



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## ADAMTS13 ACTIVITY

	Survey	No.	Mean (U/dL)	CV	Range
< 10 U/dL	2014-3	67	8.1	30.6%	0 – 19
20 U/dL	2014-1	61	16	23.1%	8 - 144
	2014-2	70	16	21.2%	6 - 38
40 U/dL	2014-1	62	35	21.5%	16 – 67
	2014-2	70	34	15.3%	15 – 55
90 U/dL	2014-3	67	90	12.3%	61 - 129

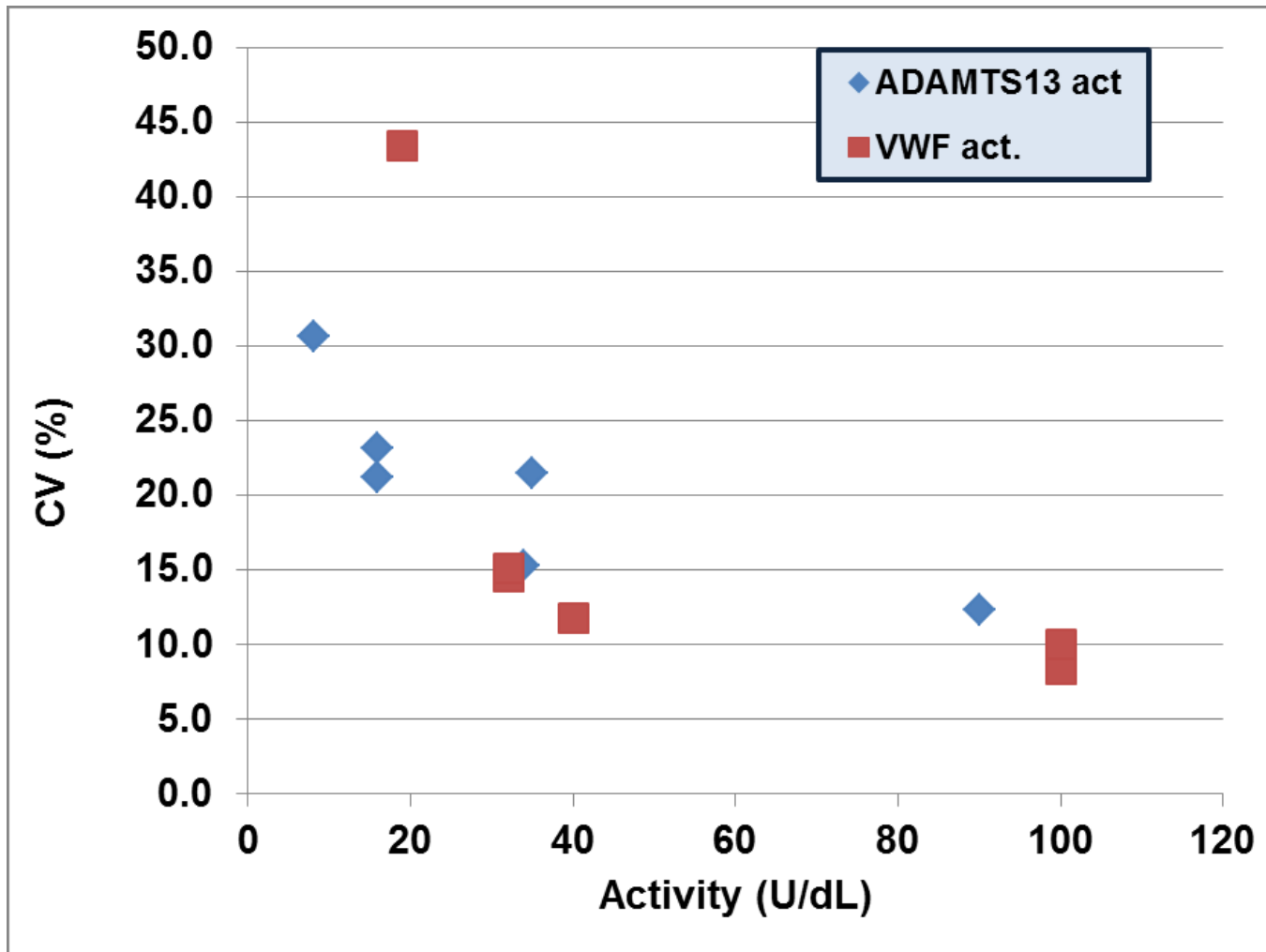


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# ADAMTS13 ACTIVITY





# ADAMTS13 ACTIVITY

	No.	< 10 (U/dL)	CV (%)	20 (U/dL)	CV (%)	40 (U/dL)	CV (%)	90 (U/dL)	CV (%)
FRET	20-24	8.4	38.0	17	30.7	36	23.7	94	10.7
EIA	36-45	8.5	20.5	16	14.2	34	19.2	88	13.6



# ADAMTS13 ACTIVITY

	No.	< 10 (U/dL)	CV (%)	20 (U/dL)	CV (%)	40 (U/dL)	CV (%)	90 (U/dL)	CV (%)
I	6-10	12	45.1	17	38.5	36	10.1	97	11.5
T	34-37	8.5	16.9	16	11.9	33	14.2	89	11.7

**I = Immucor**

**T = Technoclone**



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# ADAMTS13 ACTIVITY

	<b>90</b> <b>(U/dL)</b>	<b>CV</b> <b>(%)</b>	<b>WHO</b> <b>1<sup>st</sup></b>	<b>CV</b> <b>(%)</b>
<b>Number</b>	<b>67</b>		<b>33</b>	
<b>Overall</b>	<b>90</b>	<b>12.3</b>	<b>91</b>	<b>12.9</b>
<b>FRET</b>	<b>94</b>	<b>10.7</b>	<b>92</b>	<b>13.2</b>
<b>EIA</b>	<b>88</b>	<b>13.6</b>	<b>87</b>	<b>10.4</b>

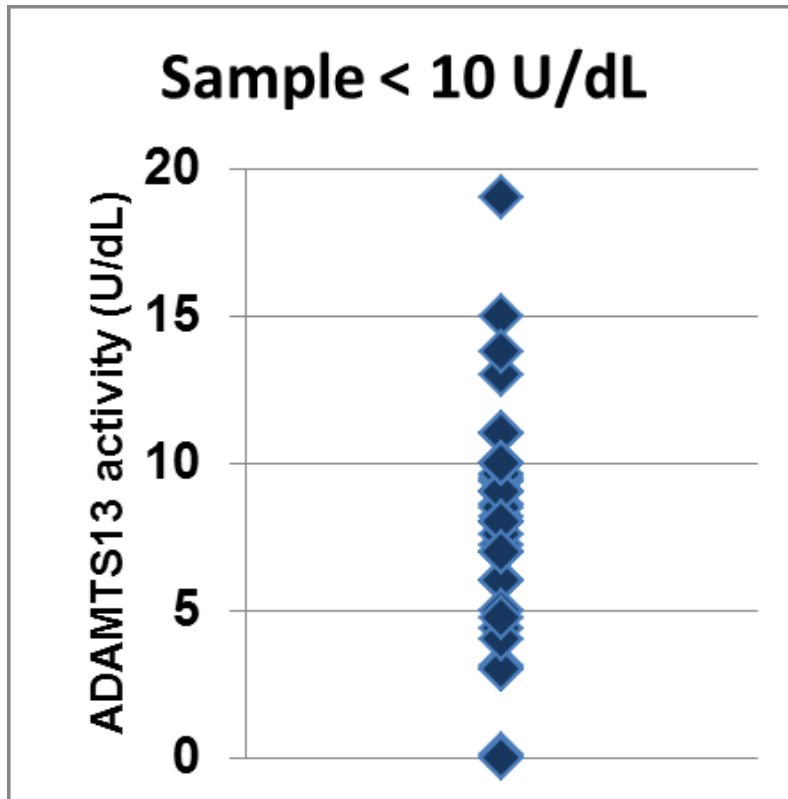


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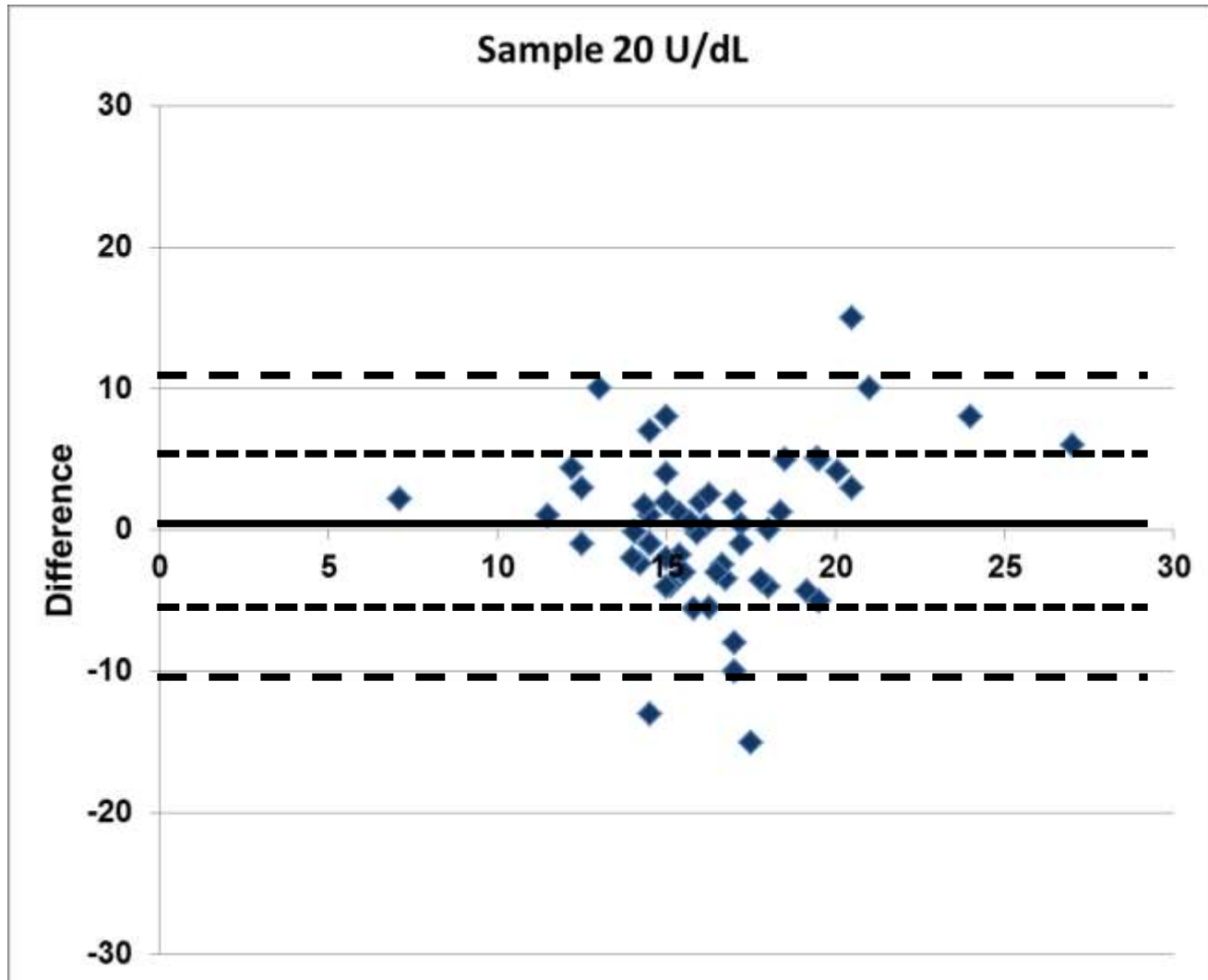
# ADAMTS13 ACTIVITY



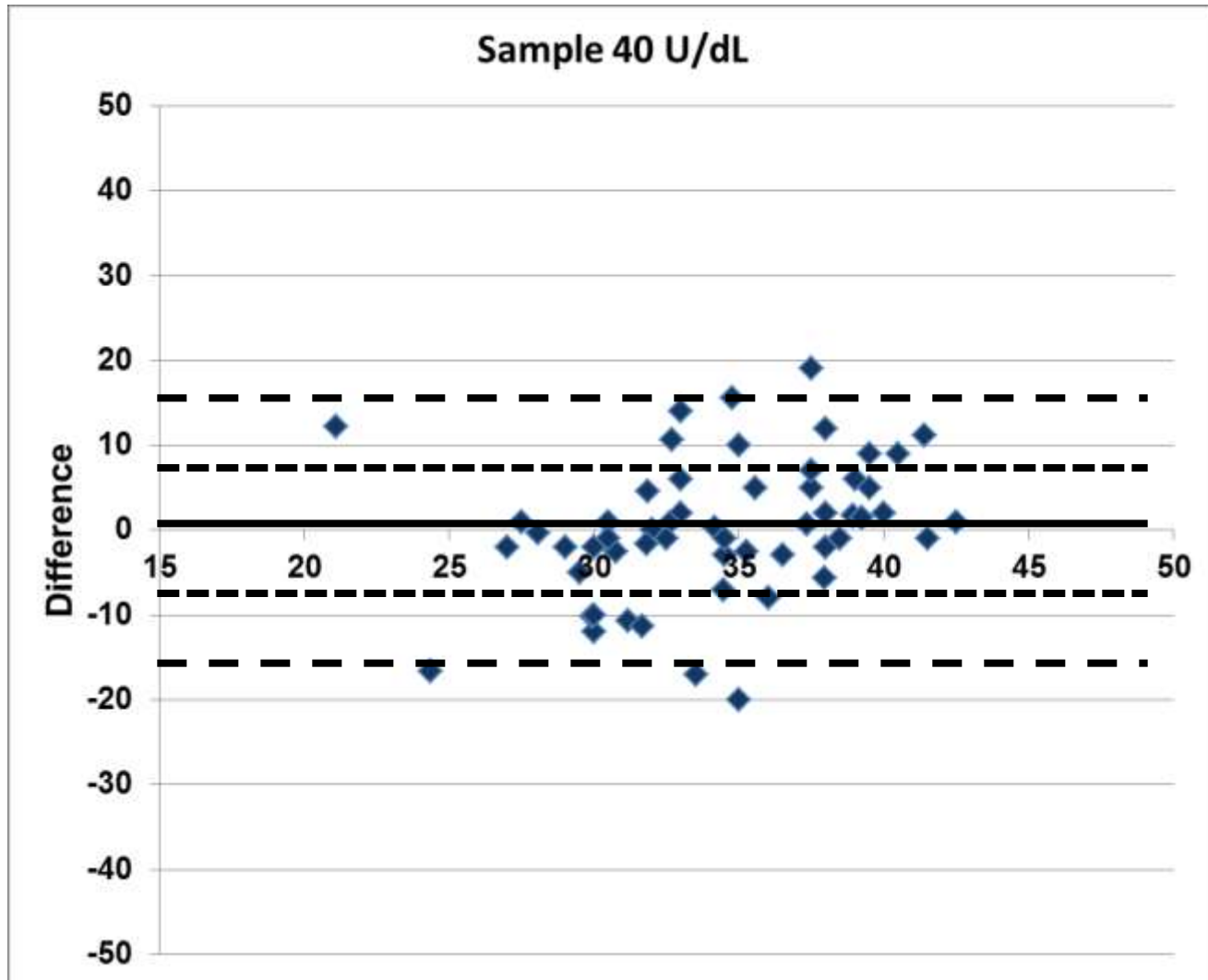
	> 10%
Overall	9%
FRET	23%
EIA	6%



# ADAMTS13 ACTIVITY



# ADAMTS13 ACTIVITY



# ADAMTS13 INHIBITOR

	No.	Mean (U/mL)	CV (%)	Range
Negative	26	0.3	-	0.0 – 9.0
Positive (6 U/mL)	34	5.8	78	0.0 – 15.1

**Negative sample :**

- 15 gave a positive result
- 12 gave a result < [value]
- 11 reported 0 U/mL

**Positive sample:**

- 4 gave a result < [value]
- 3 reported 0 U/mL



# ADAMTS13 INHIBITOR

Anti-ADAMTS13 antibodies					
		No.	Mean	CV	Range
7.5-10 U/mL	2014-3	28 (30)	9.9	46.3%	0.0 – 30.0 (3)
2.5-5 U/mL	2014-3	28 (30)	4.3	43.9%	0.0 – 10.6 (5)
Functional ADAMTS13 inhibitor					
7.5-10 BU/mL	2014-3	11 (16)	0.9	95.3%	0.0 – 34.0 (5)
2.5-5 BU/mL	2014-3	7 (16)	0.8		0.0 – 7.0 (10)





## Concluding remarks

- With the number of participants in the ADAMTS13 surveys a fairly good interlaboratory comparison can be made.
- For the ADAMTS13 activity the individual reproducibility seems to be assay-group dependent at least at lower concentrations (more samples at these low levels should be evaluated in future surveys on ADAMTS13)
- For the ADAMTS13 inhibitor there are two types of assays, the functional inhibitor and the anti-ADAMTS13 antibodies. Due to different specific assay characteristics these assays are not good comparable.



# Thank you for your attention



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