# ECAT FOUNDATION

# **External quality Control for Assays and Tests**

## With a focus on Thrombosis and Haemostasis

# REPORT



# SURVEY 2024-M3 Main Labcode 1492

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External quality Control for Assays and Tests With a focus on Thrombosis and Haemostasis

Version:

1.0.0

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Date of Issue	:	26-October-2024
Survey	:	2024-M3
Report	:	Main

Note:

In the Survey Manual 2024 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2024 should be considered as an integral part of this survey report.

Please notice the information regarding the homogeneity of samples used and the between-laboratory variation in the paragraph on the statistical evaluation of the Survey Manual.

#### General Information

#### Complaints

Any complaints regarding this survey report should be reported to the ECAT before **December 12th, 2024.** Complaints received after this date will not be taken into consideration.

#### Multiple instruments

From 2019 you have the possibility to submit per parameter results for three different instruments and or methods. However, some participants have submitted three times the same results, suggesting that this are separate results. This is <u>not</u> the case and may affect the statistical analysis. We have excluded the results from the second and third test system in the statistical analysis. Do not submit multiple times the same results anymore in future surveys.

#### Exclusion of results

Results < [value] or > [value] are excluded in the statistical analysis.

When other results (e.g. deviating results) are excluded in the statistical analysis, these results are placed between brackets.

This report is authorized by: Dr. M.J. van Essen-Hollestelle (Programme Expert)

<u>Note</u>: The actual Survey Manual can be downloaded by going to the "Participant Area" of the ECAT website, login and go to the option "View Documents".

#### ECAT Foundation

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	OVERVIEW Z-SC	ORES				
$\leq$ Z-score $\leq$ UV: Ne $3$ )	eed attention (-3 < Z-score < -2 or 3	2 < Z-score <		-		≥ 3)
						Bivarate
Parameter	Sample	Test System	Total	Assay	Method	Analysis
ADAMTS13 Activty	24.166	1	-0.72	-0.79	-0.79	
	24.167	1	-0.94	-0.98	-1.01	
	Parameter	≤ Z-score ≤ UV: Need attention (-3 < Z-score < -2 or 2 3) Parameter Sample ADAMTS13 Activty 24.166	Parameter     Sample     Test System       ADAMTS13 Activity     24.166     1	SZ-score S UV: Need attention (-3 < Z-score < -2 or 2 < Z-score < UV BV Parameter Sample Test System Total ADAMTS13 Activty 24.166 1 -0.72	<ul> <li>≤ Z-score ≤ UV: Need attention (-3 &lt; Z-score &lt; -2 or 2 &lt; Z-score &lt; UV: Unsatisfactory BV: Unacceptable</li> <li>Parameter Sample Test System Total Assay</li> <li>ADAMTS13 Activity 24.166 1 -0.72 -0.79</li> </ul>	<ul> <li>≤ Z-score ≤ UV: Need attention (-3 &lt; Z-score &lt; -2 or 2 &lt; Z-score &lt; UV: Unsatisfactory (Z-score ≤ -3 or BV: Unacceptable</li> <li>Parameter</li> <li>ADAMTS13 Activity</li> <li>24.166</li> <li>-0.72</li> <li>-0.79</li> <li>-0.79</li> </ul>



ADAMTS13 - I

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Sample No       24.166         Sample Details       Normal Coagulation Control Plasma         Prior Use       None         Unit       % or IU/dL         Expiry Date       31-October-2025         Homogeneity       0.9 %         For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178         Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when subir results. These results were excluded in the statistical evaluation.				
Prior Use       None         Unit       % or IU/dL         Expiry Date       31-October-2025         Homogeneity       0.9 %       Homogeneity Parameter       APTT         For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178       Response Rate       94 %         Comments       Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when substantiation in the survey is a statistical to be and the statistical evaluation in the survey is a statistical evaluation in the statistical evaluation in the survey is a statistical evaluation in the survey is a statistical evaluation in the surve	Sample No	24.166		
Unit       % or IU/dL         Expiry Date       31-October-2025         Homogeneity       0.9 %       Homogeneity Parameter       APTT         For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178       Response Rate       94 %         Comments       Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when substances	Sample Details	Normal Coagulation Control Plasma		
Expiry Date       31-October-2025         Homogeneity       0.9 %       Homogeneity Parameter       APTT         For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178       Response Rate       94 %         Comments       Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when substances	Prior Use	None		
Homogeneity       0.9 %       Homogeneity Parameter       APTT         For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178       Response Rate       94 %         Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when substances	Unit	% or IU/dL		
For any method used for the measurement of this parameter with a CV ≤ 3.0% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.         Number of Participants       190         Number of Responders       178         Response Rate       94 %         Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when sub-	Expiry Date	31-October-2025		
homogeneity could not be met and the Z-scores should be interpreted with caution. See for furth the paragraph on the statistical evaluation in the Survey Manual.Number of Participants190Number of Responders178Comments94 %Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when substances	Homogeneity	0.9 %	Homogeneity Parameter	APTT
Number of Responders178Response Rate94 %CommentsMultiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when sub-		homogeneity could not be met and th	he Z-scores should be interpreted	
Comments         Multiple participants (labcodes 305, 1052 and 9045) selected the wrong unit when sub-	Number of Participants	190		
	Number of Responders	178	Response Rate	94 %
	Comments		, ,	0 0

The following participant reported a deviating result which was excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the samples 24.166 and 24.167: labcode **215** 

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	196	0	0	1	3

Normal

#### Your Classification

#### **Own Reagent**

e ini iteagent											
	n	assigned	Uncert.	CV (%)	Range	your	z-score	your	z-score	your	z-score
		value				result		result		result	
Total Group	187	95	1.23	14.1	41 - 146	85.6	-0.72				
CLIA/FIA	79	96	1.91	14.1	67 - 128	85.6	-0.79				
Werfen Acustar activity	78	96	1.93	14.2	67 - 128	85.6	-0.79				



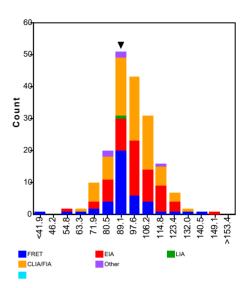
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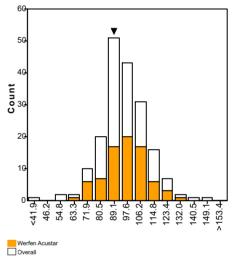
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### **Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
Total Group	187	95	1.23	14.1	41 - 146
FRET	43	91	2.09	12.1	41 - 139
Homemade	13	92	5.32	16.7	65 - 139
Immucor activity	2	126			120 - 133
Other	5	73			41 - 104
Sekisui Actifluor activity	2	91			88 - 93
Technoclone Technofluor activity	21	90	1.43	5.8	80 - 111
Enzyme Immuno Assay	59	98	2.26	14.2	55 - 146
Homemade	1	84			-
Technoclone Technozym activity	57	98	2.23	13.7	75 - 146
Technoclone Technozym activity/antigen	1	55			-
Latex Immuno Assay	1	85			-
Homemade	1	85			-
CLIA/FIA	79	96	1.91	14.1	67 - 128
Other	1	86			-
Other	5	86			84 - 117
Homemade	2	85			84 - 86
Other	3	92			84 - 117







ADAMTS13 - I

## ADAMTS13 Activity

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Sample No	24.167		
Sample Details	Plasma with an ADAMTS13 activity le	evel between 10 and 20%	
Prior Use	None		
Unit	% or IU/dL		
Expiry Date	30-April-2026		
Homogeneity	2.4 %	Homogeneity Parameter	ADAMTS13
		nould be interpreted with caution.	V ≤ 8.0% the criterion for homogeneity . See for further details the paragraph
Number of Participants	190		
Number of Responders	178	Response Rate	94 %
Comments	Multiple participants (labcodes <b>30</b> results. These results were exclu	. ,	he wrong unit when submitting the n.

The following participant reported a deviating result which was excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the samples 24.166 and 24.167: labcode **215** 

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	2	2	8	185	3

Your Classification

on Abnormal

#### **Own Reagent**

	n	assigned	Uncert.	CV (%)	Range	your	z-score	your	z-score	your	z-score
		value				result		result		result	
Total Group	192	13	0.23	19.5	0 - 43	10.8	-0.94				
CLIA/FIA	81	13	0.28	15.9	9 - 18	10.8	-0.98				
Werfen Acustar activity	80	13	0.28	15.7	9 - 18	10.8	-1.01				



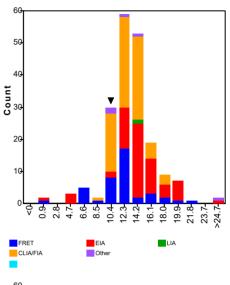
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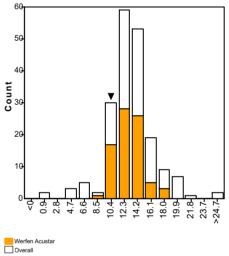
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## Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	192	13	0.23	19.5	0 - 43
FRET	41	12	0.62	26.9	0 - 22
Homemade	11	11	1.45	34.8	0 - 22
Immucor activity	4	15			11 - 19
Other	3	12			6 - 15
Sekisui Actifluor activity	2	9.0			6.0 - 12.0
Technoclone Technofluor activity	21	12	0.42	13.0	6 - 17
Enzyme Immuno Assay	64	15	0.39	17.2	0 - 34
Homemade	1	13			-
Technoclone Technozym activity	62	15	0.39	16.8	5 - 34
Technoclone Technozym activity/antigen	1	0.0			-
Latex Immuno Assay	1	15			-
Homemade	1	15			-
CLIA/FIA	81	13	0.28	15.9	9 - 18
Other	1	9.9			-
Other	5	12			10 - 43
Homemade	2	28			12 - 43
Other	3	11			10 - 14

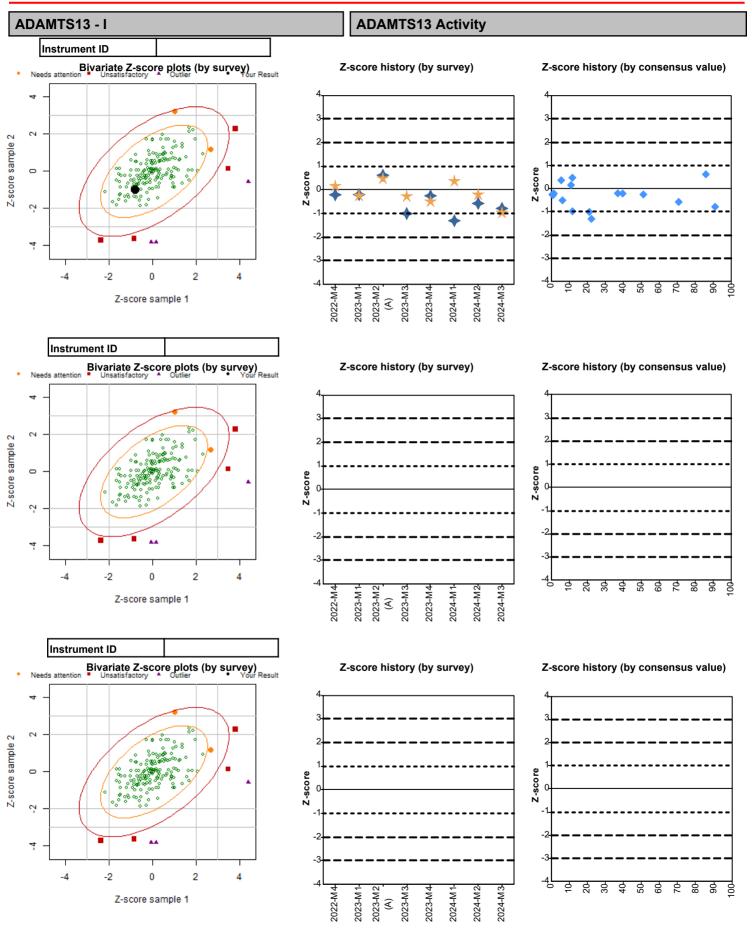






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## ADAMTS13 antigen

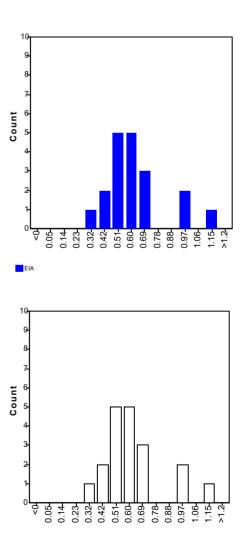
ter APTT
vith a $CV \leq 3.0\%$ the criterion for
erpreted with caution. See for further details
al.
12 %
he wrong unit when submitting the results.

The following participant reported a result in ng/mL, which was excluded in the statistical analysis: 1703 : 688.6 ng/mL

Classification Overview		Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
	Total	19	1	1	0	1

### **Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	19	0.59	0.05	27.4	0.33 - 1.14
Technozym Technozym activity/antigen	3	0.95			0.47 - 1.14
Technozym Technozym antigen	16	0.57	0.04	21.6	0.33 - 0.97



Overall



ADAMTS13 - I

# ADAMTS13 antigen

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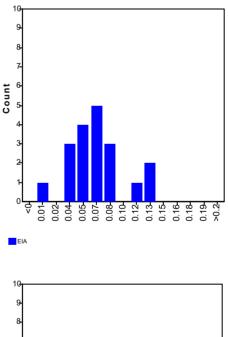
Sample No	24.167					
Sample Details	Plasma with an ADAMTS13 activity level between 10 and 20%					
Prior Use	None					
Unit	IU/mL					
Expiry Date	30-April-2026					
Homogeneity	2.4 %	Homogeneity Parameter	ADAMTS13			
	For any method used for the measurement of this parameter with a <b>CV ≤ 8.0%</b> the criterion for homogeneit could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.					
Number of Participants	190					
Number of Responders	22	Response Rate	12 %			
Comments	Multiple participants (labcodes 950 and 1511) selected the wrong unit when submitting the result					
	These results were excluded in the statistical evaluation.					
	The following participant reported	- regult in na/ml which was	evaluated in the statistical analysis.			

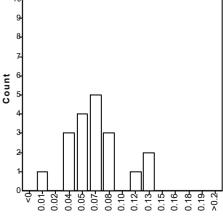
The following participant reported a result in ng/mL, which was excluded in the statistical analysis: **1703** : 61.3 ng/mL

Classification	Normal	BorderLine	Borderline Abnorm		No
Overview		normal	abnormal		classification
Total	0	1	0	20	1

### **Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	19	0.07	0.01	40.5	0.00 - 0.13
Technozym Technozym activity/antigen	3	0.13			0.08 - 0.13
Technozym Technozym antigen	16	0.06	0.01	33.4	0.00 - 0.12





Overall



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