

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2024-M3**

**Main**

**Labcode 1492**

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 **not** 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)

**Note:** 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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General terms of delivery are applicable to all our services.

**OVERVIEW Z-SCORES**

■ UV: Satisfactory ( $-2 \leq Z\text{-score} \leq 2$ )     
 ■ UV: Need attention ( $-3 < Z\text{-score} < -2$  or  $2 < Z\text{-score} < 3$ )     
 ■ UV: Unsatisfactory ( $Z\text{-score} \leq -3$  or  $\geq 3$ )  
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
ADAMTS13 - I	ADAMTS13 Activity	24.166	1	-0.72	-0.79	-0.79	
		24.167	1	-0.94	-0.98	-1.01	

<b>ADAMTS13 - I</b>	<b>ADAMTS13 Activity</b>
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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 % **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 further details 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 submitting the results. These results were excluded in the statistical evaluation.

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
<b>Total</b>	196	0	0	1	3

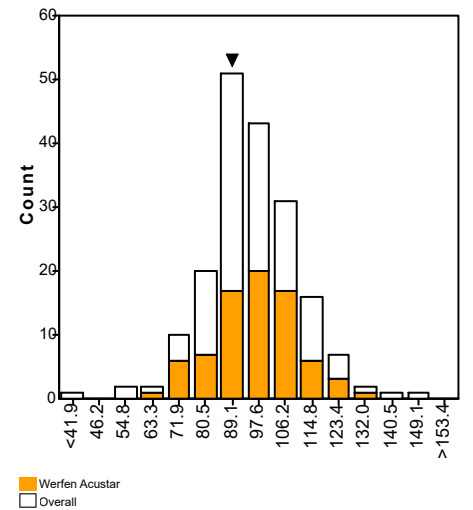
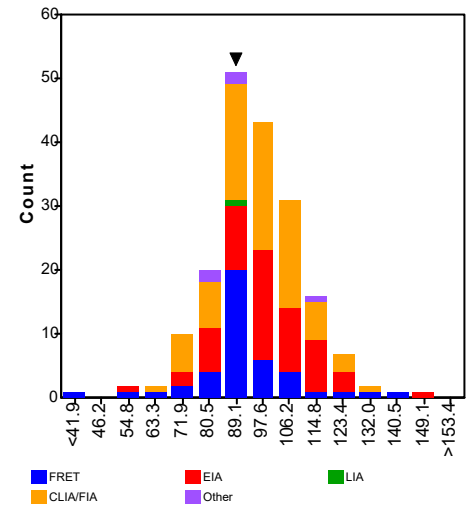
**Your Classification** Normal

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	187	95	1.23	14.1	41 - 146	85.6	-0.72				
<b>CLIA/FIA</b>	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				

**Other Reagents**

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



<b>ADAMTS13 - I</b>	<b>ADAMTS13 Activity</b>
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**Sample No** 24.167  
**Sample Details** Plasma with an ADAMTS13 activity level between 10 and 20%  
**Prior Use** None  
**Unit** % or IU/dL  
**Expiry Date** 30-April-2026  
**Homogeneity** 2.4 % **Homogeneity Parameter** ADAMTS13  
 For any method used for the measurement of this parameter with a CV ≤ 8.0% the criterion for homogeneity 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** 178 **Response Rate** 94 %

**Comments** Multiple participants (labcodes **305, 1052 and 9045**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

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
<b>Total</b>	2	2	8	185	3

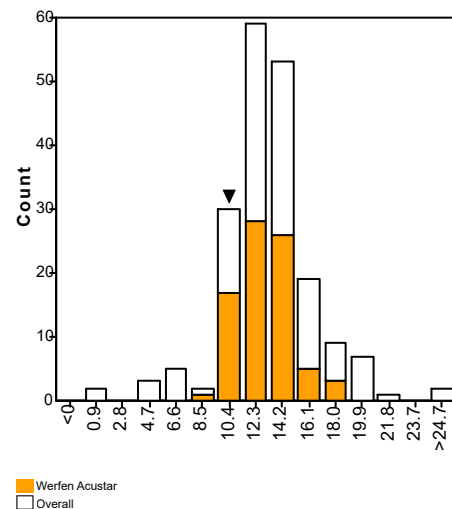
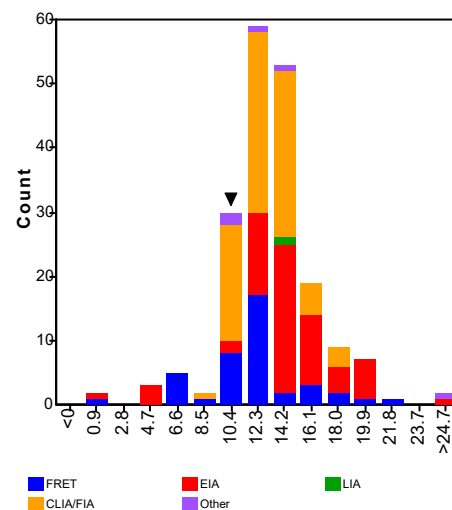
**Your Classification** Abnormal

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	192	13	0.23	19.5	0 - 43	10.8	-0.94				
<b>CLIA/FIA</b>	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				

**Other Reagents**

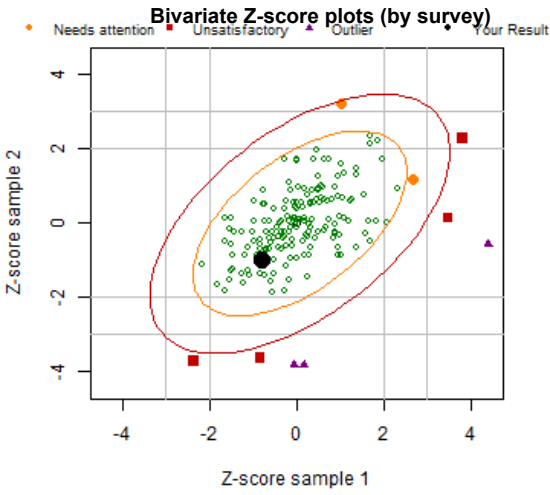
	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	192	13	0.23	19.5	0 - 43
<b>FRET</b>	41	12	0.62	26.9	0 - 22
<b>Homemade</b>	11	11	1.45	34.8	0 - 22
<b>Immucor activity</b>	4	15			11 - 19
<b>Other</b>	3	12			6 - 15
<b>Sekisui Actifluor activity</b>	2	9.0			6.0 - 12.0
<b>Technoclone Technofluor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



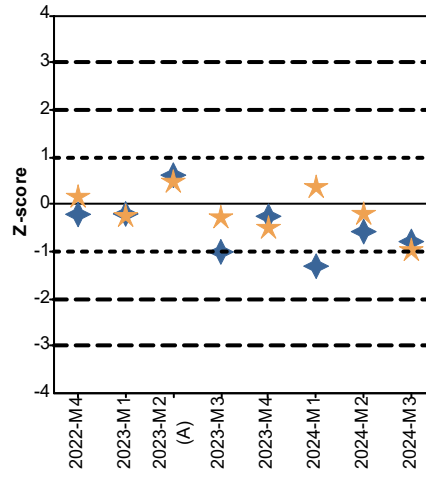
ADAMTS13 - I

ADAMTS13 Activity

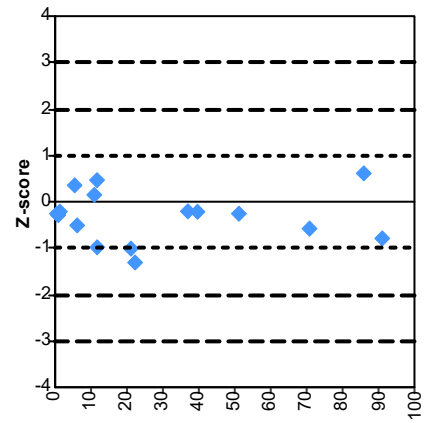
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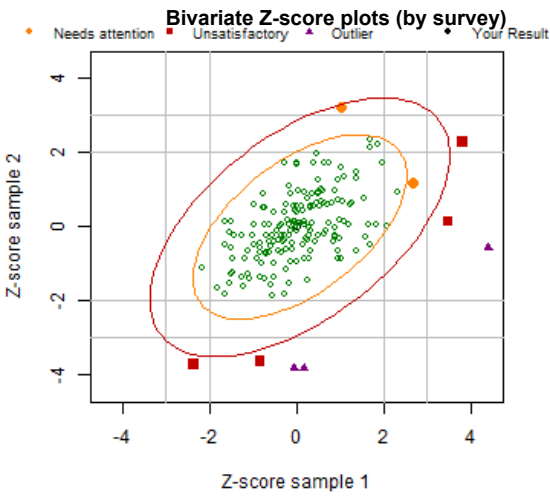
Z-score history (by survey)



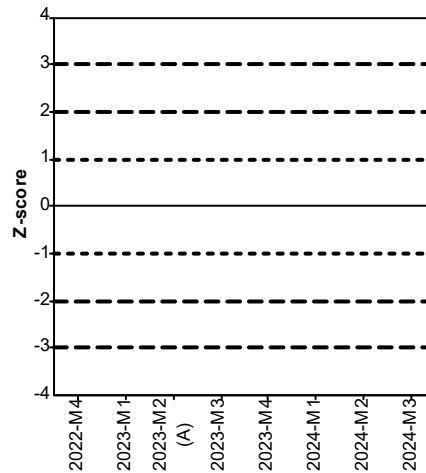
Z-score history (by consensus value)



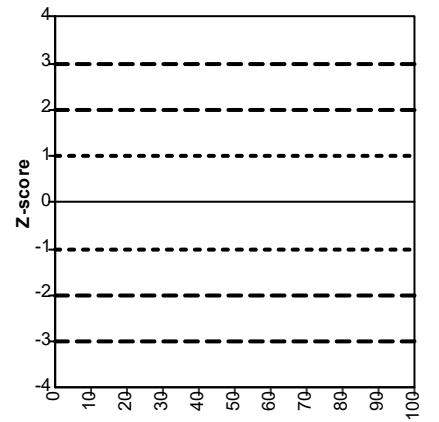
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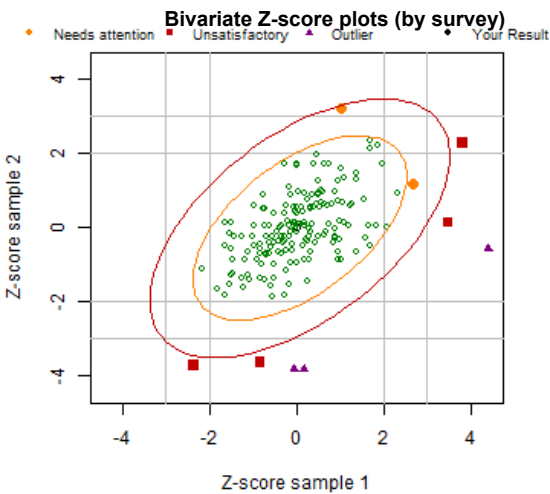
Z-score history (by survey)



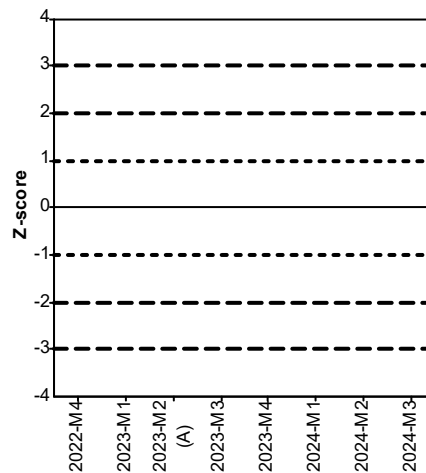
Z-score history (by consensus value)



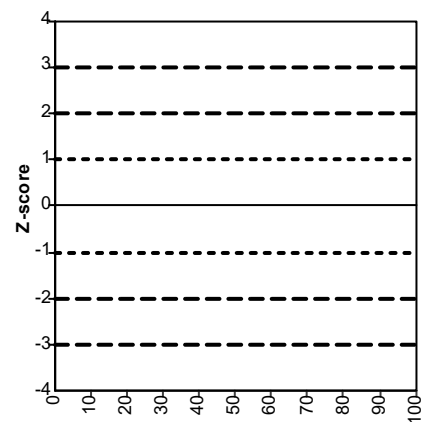
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)





<b>ADAMTS13 - I</b>	<b>ADAMTS13 antigen</b>
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**Sample No** 24.166  
**Sample Details** Normal Coagulation Control Plasma  
**Prior Use** None  
**Unit** IU/mL  
**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 further details the paragraph on the statistical evaluation in the Survey Manual.

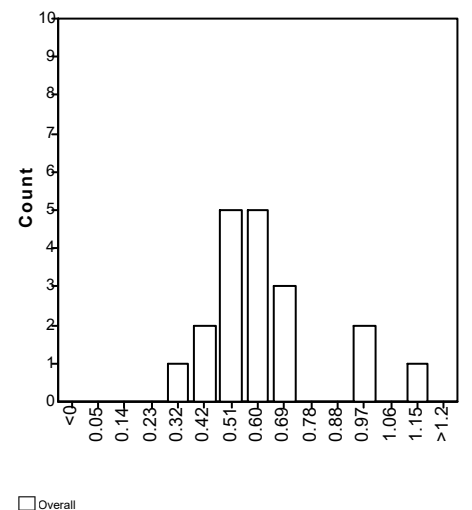
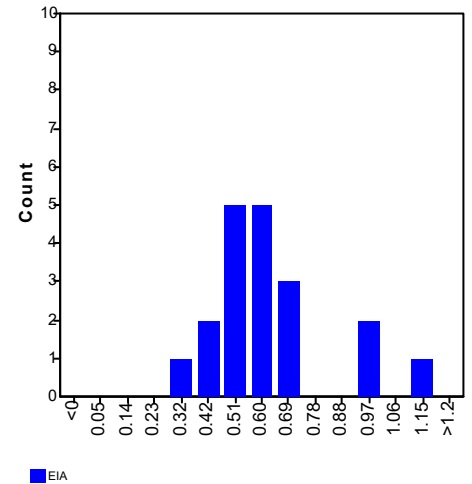
**Number of Participants** 190  
**Number of Responders** 22 **Response Rate** 12 %  
**Comments** Multiple participants (labcodes **950 and 1511**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

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
<b>Total</b>	19	1	1	0	1

**Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
<b>Enzyme Immuno Assay</b>	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



<b>ADAMTS13 - I</b>	<b>ADAMTS13 antigen</b>
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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 **CV ≤ 8.0%** the criterion for homogeneity 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.

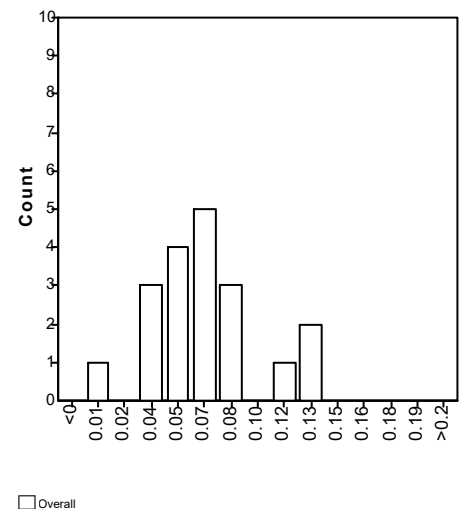
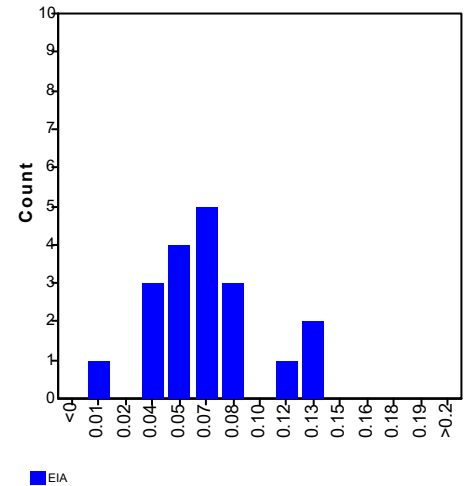
**Number of Participants** 190  
**Number of Responders** 22 **Response Rate** 12 %  
**Comments** Multiple participants (labcodes **950 and 1511**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

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

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
<b>Total</b>	0	1	0	20	1

**Other Reagents**

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



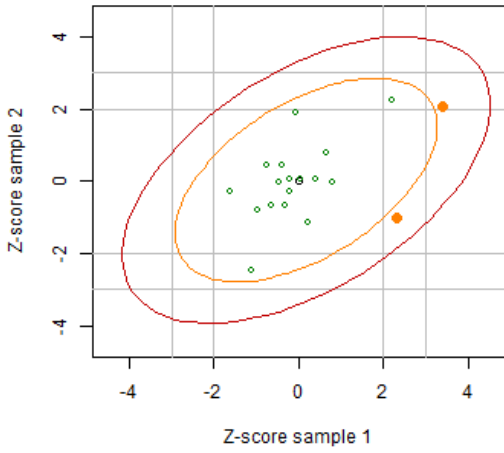
**ADAMTS13 - I**

**ADAMTS13 antigen**

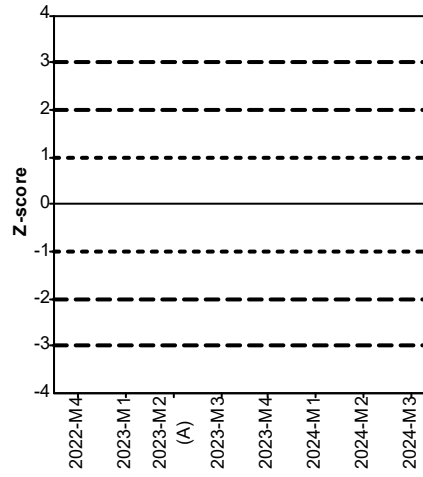
Instrument ID

**Bivariate Z-score plots (by survey)**

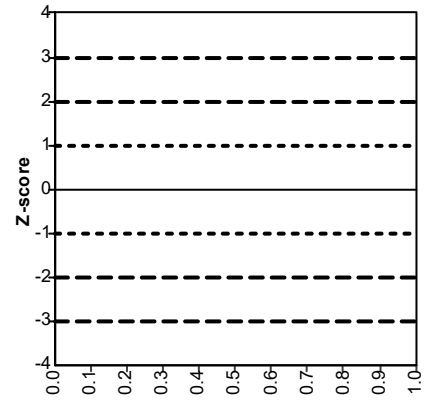
Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



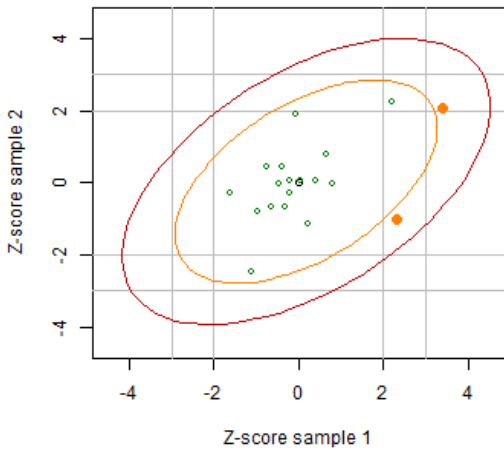
**Z-score history (by consensus value)**



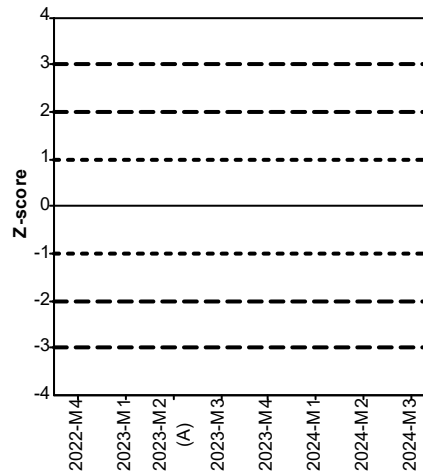
Instrument ID

**Bivariate Z-score plots (by survey)**

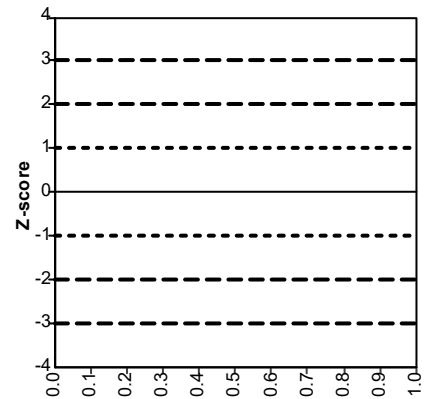
Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



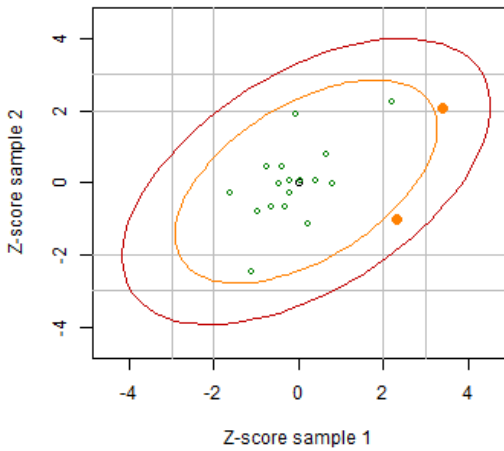
**Z-score history (by consensus value)**



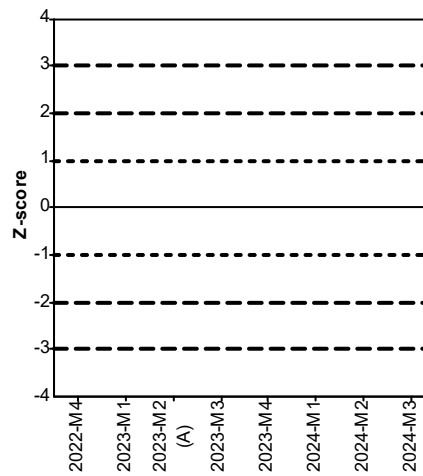
Instrument ID

**Bivariate Z-score plots (by survey)**

Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



**Z-score history (by consensus value)**

