

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2023-M3**

**Main**

**Labcode 1492**

Date of Issue : 30-oktober-2023

Survey : 2023-M3

Report : Main

#### Note:

In the Survey Manual 2023 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2023 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, 2023**.

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: A printed version of the actual Survey Manual is provided to all participants once a year. This manual can also be downloaded from the member section of the ECAT website.

#### ECAT Foundation

Director: Dr. P. Meijer  
ECAT Office  
P.O. Box 107  
2250 AC Voorschoten, The Netherlands  
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919  
E-mail: [info@ecat.nl](mailto:info@ecat.nl)  
Website: [www.ecat.nl](http://www.ecat.nl)  
VAT number: NL802836872B01

Registration number with the Chamber of Commerce (KvK) Gouda : 41174102  
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 Activty	23.152	1	-0.83	-1.00	-0.97	
		23.153	1	-0.41	-0.28		

<b>ADAMTS13 - I</b>	<b>ADAMTS13 Activity</b>
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**Sample No** 23.152  
**Sample Details** Plasma with an ADAMTS13 activity level between 20 and 30%  
**Prior Use** None  
**Unit** % or IU/dL  
**Expiry Date** 30-april-2025  
**Homogeneity** 3.1 % **Homogeneity Parameter** ADAMTS13 act  
 For any method used for the measurement of this parameter with a **CV ≤ 10.3%** 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** 166  
**Number of Responders** 153 **Response Rate** 92 %  
**Comments** None.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
<b>Total</b>	7	4	13	148	1

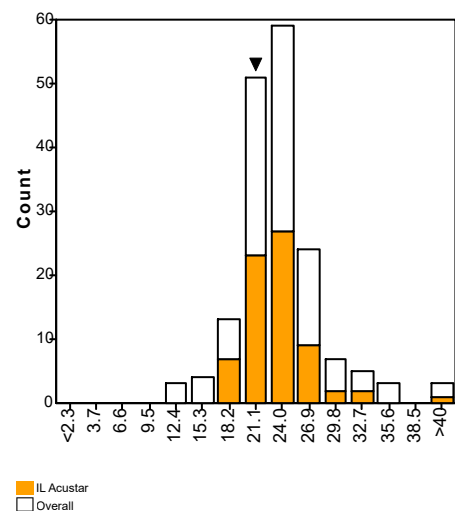
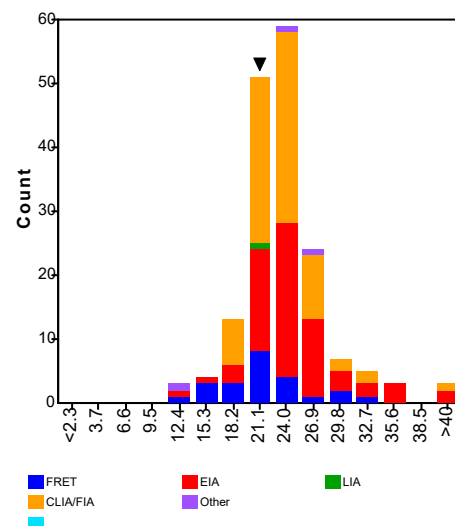
**Your Classification** Abnormal

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	172	23	0.32	14.5	13 - 54	20.5	-0.83				
<b>CLIA/FIA</b>	78	23	0.37	11.2	18 - 46	20.5	-1.00				
IL Acustar ADAMTS13 activity	71	23	0.40	11.8	18 - 46	20.5	-0.97				

**Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	172	23	0.32	14.5	13 - 54
<b>FRET</b>	23	21	1.23	22.3	13 - 34
<b>Homemade</b>	12	20	1.64	22.5	13 - 29
<b>Immucor ADAMTS13 activity</b>	4	22			16 - 30
<b>Other</b>	6	21			17 - 26
<b>Sekisui Actifluor ADAMTS13 activity</b>	1	34			-
<b>Enzyme Immuno Assay</b>	67	24	0.58	15.5	13 - 54
<b>Homemade</b>	2	25			18 - 31
<b>Other</b>	1	25			-
<b>Technoclone ADAMTS13 activity</b>	63	24	0.55	14.3	13 - 54
<b>Technoclone ADAMTS13 activity/antigen</b>	1	15			-
<b>Latex Immuno Assay</b>	1	21			-
<b>Homemade</b>	1	21			-
<b>CLIA/FIA</b>	78	23	0.37	11.2	18 - 46
<b>Technoclone Technofluor ADAMTS13 ac</b>	7	23			21 - 26
<b>Other</b>	3	23			14 - 26
<b>Homemade</b>	2	20			14 - 26
<b>Other</b>	1	23			-



<b>ADAMTS13 - I</b>	<b>ADAMTS13 Activity</b>
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**Sample No** 23.153  
**Sample Details** Plasma with an ADAMTS13 activity level < 1%  
**Prior Use** None  
**Unit** % or IU/dL  
**Expiry Date** 30-april-2025  
**Homogeneity** 62.6 % **Homogeneity Parameter** ADAMTS13 act  
 For any method used for the measurement of this parameter with a **CV ≤ 208.7%** 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** 166  
**Number of Responders** 153 **Response Rate** 92 %

**Comments** The following participants reported deviating results which were excluded in the statistical evaluation:  
**176** : 40%  
**610** : 13.1%  
**4560** : 11.6%

We investigated the potential effect of the high homogeneity and observed comparable interlaboratory variation results with previous similar samples used in this EQA program . Therefore, we could conclude that the high homogeneity does not effect the interlaboratory variation results for this sample .

The extreme low "between laboratory CV" for the IL Acustar ADAMTS13 activity method is caused by the fact that the majority of results had a very small distribution.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
<b>Total</b>	0	0	0	173	1

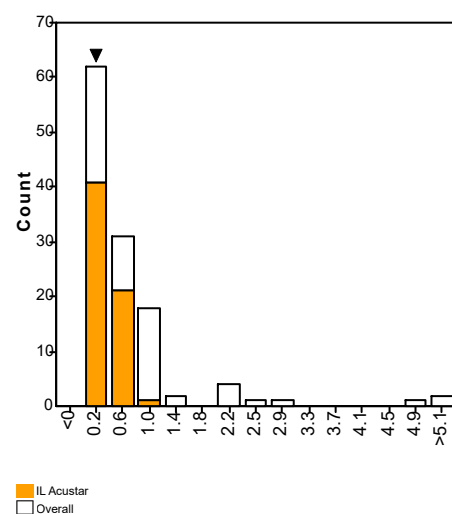
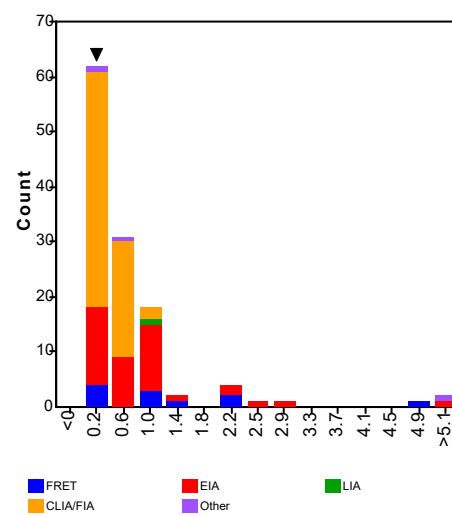
**Your Classification** Abnormal

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	122	0.5	0.04	83.9	0.0 - 6.3	0.3	-0.41				
<b>CLIA/FIA</b>	66	0.3	0.02	31.9	0.0 - 0.9	0.3	-0.28				
IL Acustar ADAMTS13 activity	63	0.3	0.00	0.0	0.0 - 0.8	0.3					

**Other Reagents**

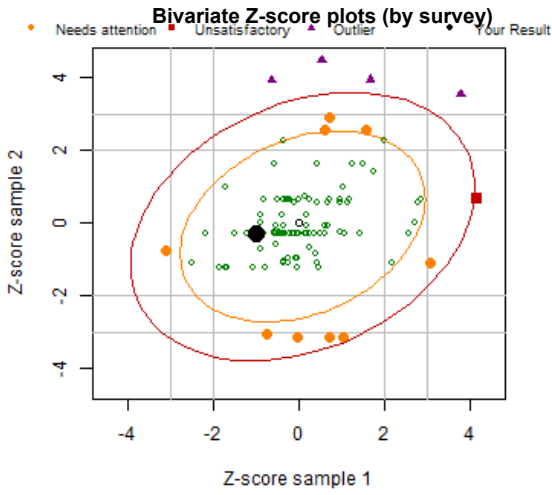
	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	122	0.5	0.04	83.9	0.0 - 6.3
<b>FRET</b>	11	1.0	0.38	104.8	0.0 - 5.0
Homemade	6	0.5			0.0 - 5.0
Immucor ADAMTS13 activity	1	1.2			-
Other	3	1.0			0.0 - 2.0
Sekisui Actifluor ADAMTS13 activity	1	1.0			-
<b>Enzyme Immuno Assay</b>	41	0.7	0.12	91.7	0.0 - 6.3
Homemade	1	1.5			-
Technoclone ADAMTS13 activity	39	0.6	0.11	88.4	0.0 - 6.3
Technoclone ADAMTS13 activity/antigen	1	0.0			-
Latex Immuno Assay	1	1.0			-
Homemade	1	1.0			-
<b>CLIA/FIA</b>	66	0.3	0.02	31.9	0.0 - 0.9
Technoclone Technofluor ADAMTS13 ac	3	0.0			0.0 - 0.9
Other	3	0.5			0.0 - 6.0
Homemade	2	3.0			0.0 - 6.0
Other	1	0.5			-



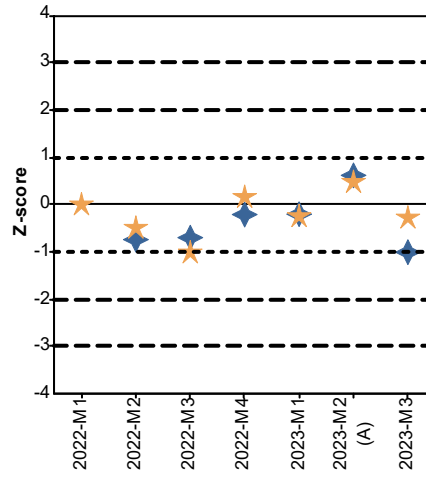
**ADAMTS13 - I**

**ADAMTS13 Activity**

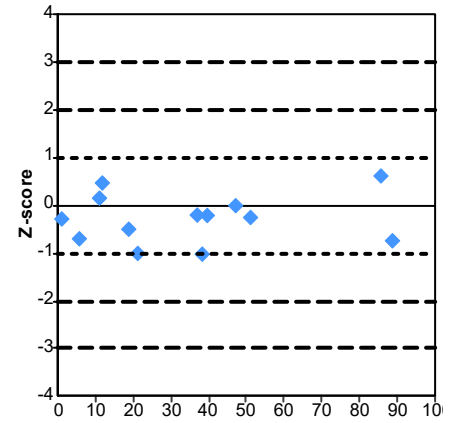
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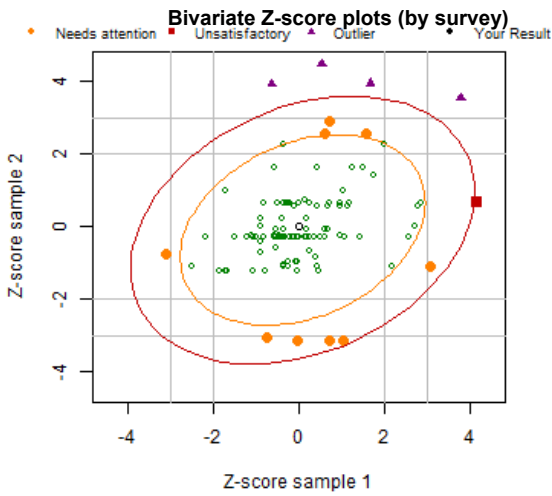
**Z-score history (by survey)**



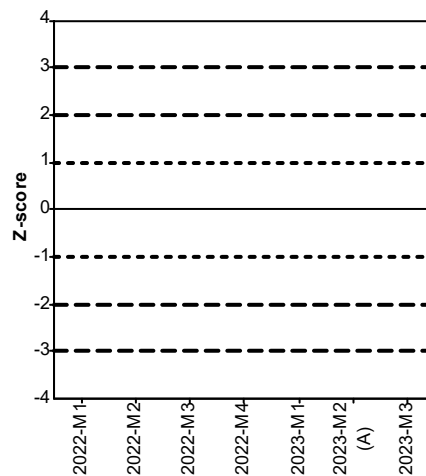
**Z-score history (by consensus value)**



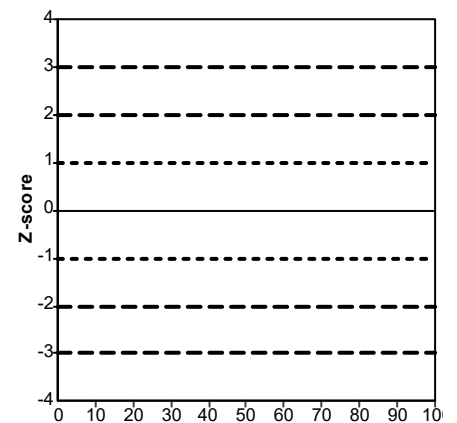
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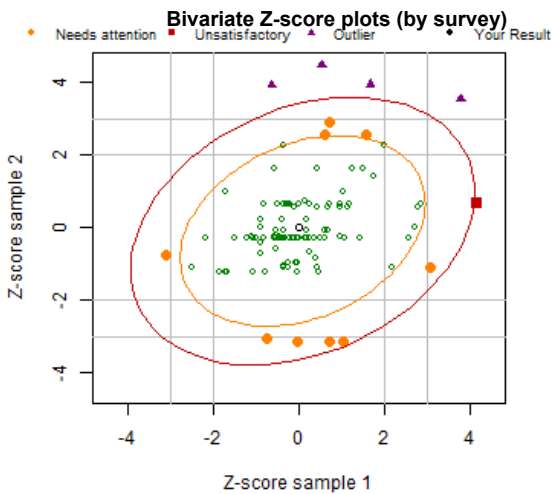
**Z-score history (by survey)**



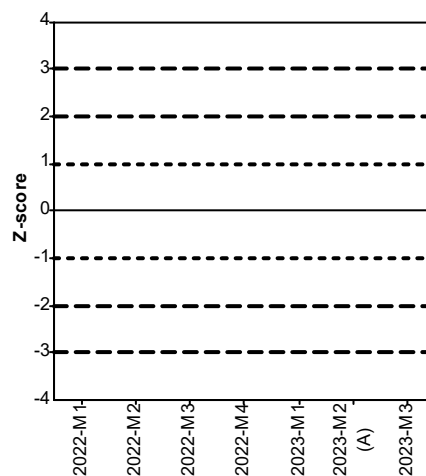
**Z-score history (by consensus value)**



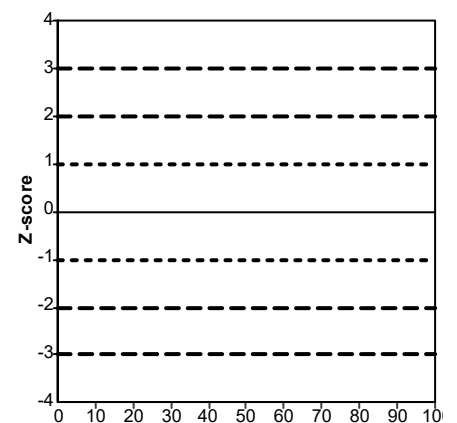
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**Z-score history (by survey)**



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





**ADAMTS13 - I**

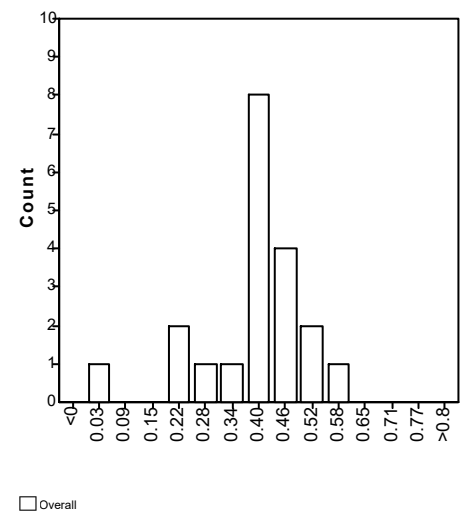
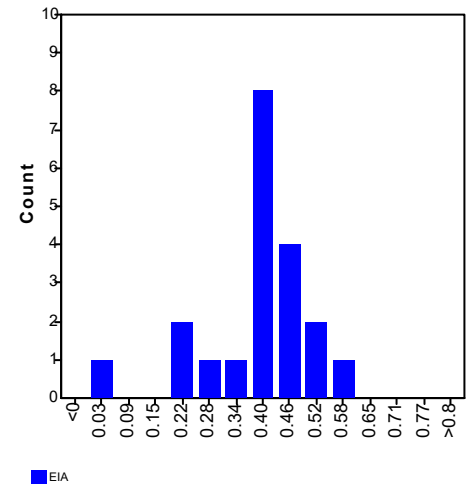
**ADAMTS13 antigen**

**Sample No** 23.152  
**Sample Details** Plasma with an ADAMTS13 activity level between 20 and 30%  
**Prior Use** None  
**Unit** IU/mL  
**Expiry Date** 30-april-2025  
**Homogeneity** 3.1 % **Homogeneity Parameter** ADAMTS13 act  
 For any method used for the measurement of this parameter with a CV ≤ 10.3% 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** 166  
**Number of Responders** 22 **Response Rate** 13 %  
**Comments** Two participants (**labcodes 1086 and 1196**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
<b>Total</b>	11	2	3	6	0

**Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
<b>Enzyme Immuno Assay</b>	20	0.40	0.03	26.5	0.04 - 0.59
<b>Technozym ADAMTS13 activity/antigen</b>	3	0.22			0.22 - 0.40
<b>Technozym ADAMTS13 antigen</b>	17	0.43	0.03	20.3	0.04 - 0.59



**ADAMTS13 - I**

**ADAMTS13 antigen**

**Sample No** 23.153  
**Sample Details** Plasma with an ADAMTS13 activity level < 1%  
**Prior Use** None  
**Unit** IU/mL  
**Expiry Date** 30-april-2025  
**Homogeneity** 62.6 % **Homogeneity Parameter** ADAMTS13 act  
 For any method used for the measurement of this parameter with a **CV ≤ 208.7%** 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.  
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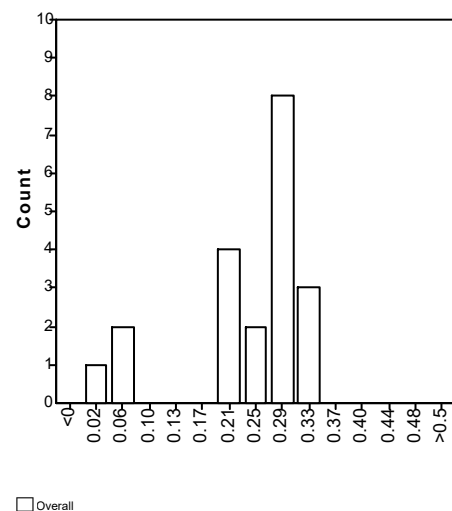
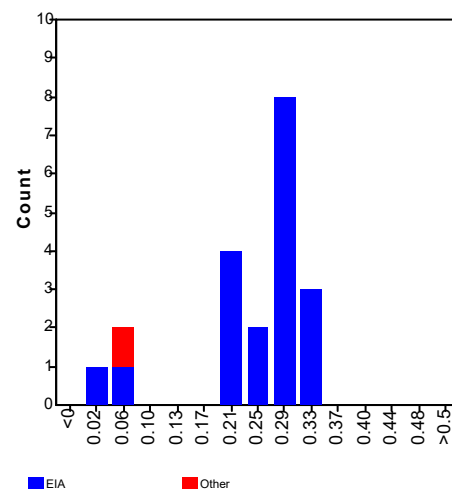
The following participant reported a deviating result which was excluded in the statistical evaluation:  
**215** : 0.418%

We investigated the potential effect of the high homogeneity and observed comparable interlaboratory variation results with previous similar samples used in this EQA program . Therefore, we could conclude that the high homogeneity does not effect the interlaboratoy variation results for this sample .

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
<b>Total</b>	1	0	4	18	0

**Other Reagents**

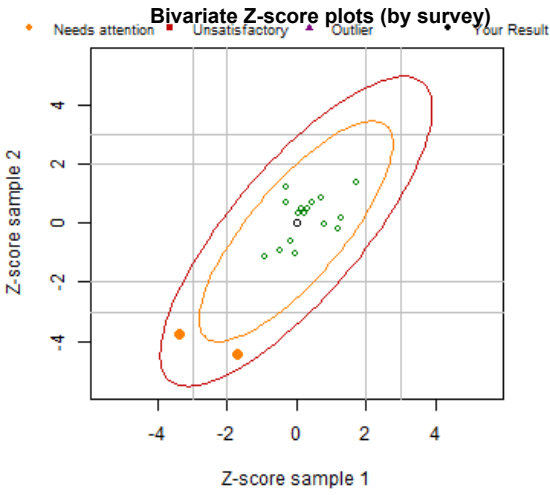
	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	20	0.25	0.02	25.5	0.01 - 0.34
<b>Enzyme Immuno Assay</b>	19	0.26	0.02	21.6	0.01 - 0.34
Technozym ADAMTS13 activity/antigen	2	0.11			0.01 - 0.20
Technozym ADAMTS13 antigen	17	0.27	0.01	17.8	0.05 - 0.34
<b>Other</b>	1	0.06			-
Homemade	1	0.06			-



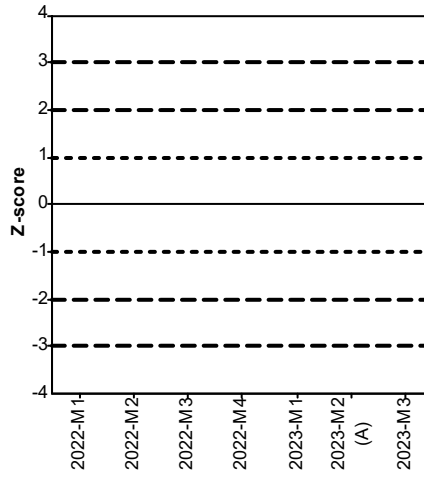
**ADAMTS13 - I**

**ADAMTS13 antigen**

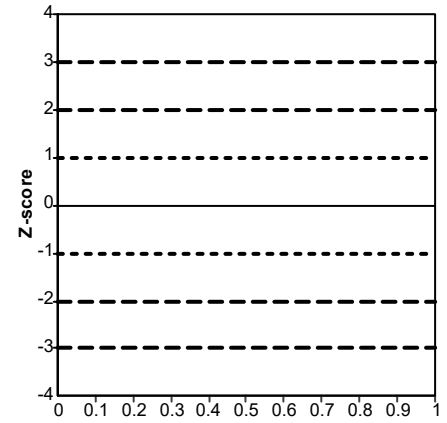
Instrument ID



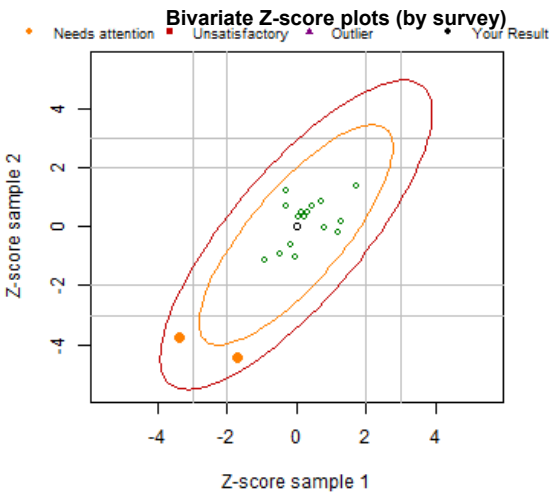
Z-score history (by survey)



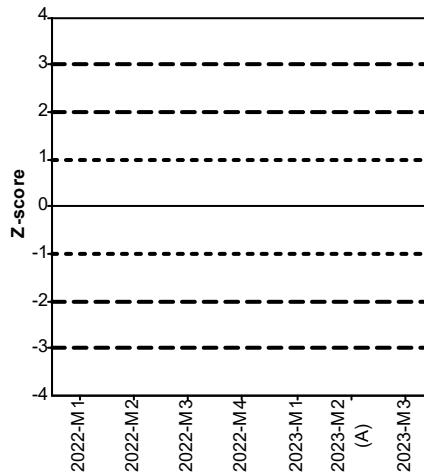
Z-score history (by consensus value)



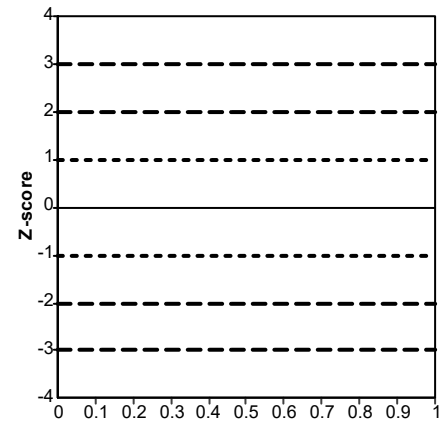
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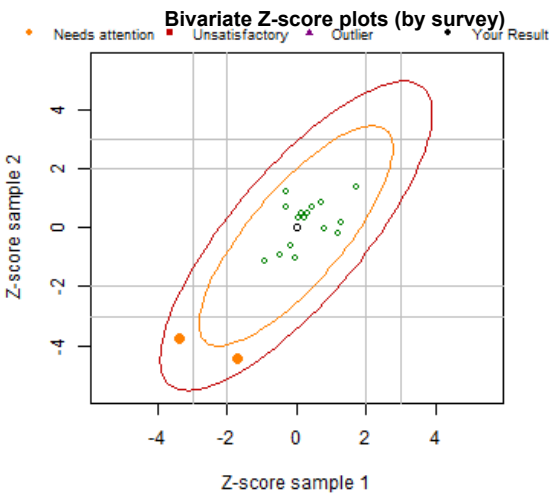
Z-score history (by survey)



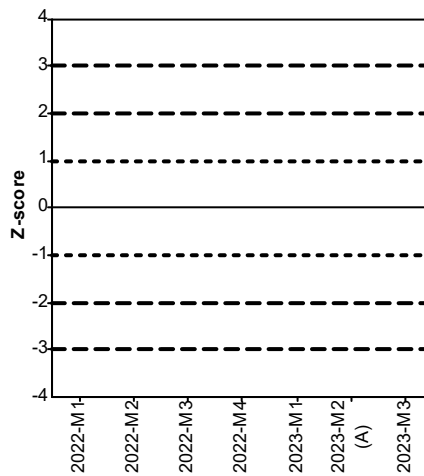
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

