

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-M1

Main

Labcode 1492

Date of Issue : 10-May-2025

Survey : 2025-M1

Report : Main

Note:

In the Survey Manual 2025 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2025 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

Exclusion of results

Results < [value] or > [value] are excluded from the statistical analysis. When other results (e.g. deviating results) are excluded from the statistical analysis, these results are placed between brackets.

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 from the statistical analysis. Do not submit multiple times the same results anymore in future surveys.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **June 24th, 2025** Complaints received after this date will not be taken into consideration.

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

Note: The current Survey Manual can be downloaded from the 'Participant Area' of the ECAT website. Login and select the option 'View Documents'.




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
Website: www.ecat.nl
VAT number: NL802836872B01

Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
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OVERVIEW Z-SCORES

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

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
ADAMTS13 - I	ADAMTS13 Activity	25.52	1	 1.25	 1.09	 1.09	

ADAMTS13 - I	ADAMTS13 Activity
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Sample No	25.51		
Sample Details	Plasma with an ADAMTS13 activity level <5%		
Prior Use	None		
Unit	% or IU/dL		
Expiry Date	30-November-2026		
Homogeneity	27.0 %	Homogeneity Parameter	ADAMTS13
	For any method used for the measurement of this parameter with a CV ≤ 90.0% 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	199		
Number of Responders	186	Response Rate	93 %
Comments	None.		

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	1	0	0	206	2

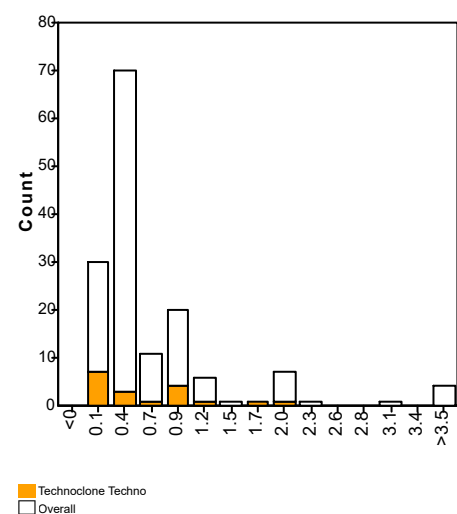
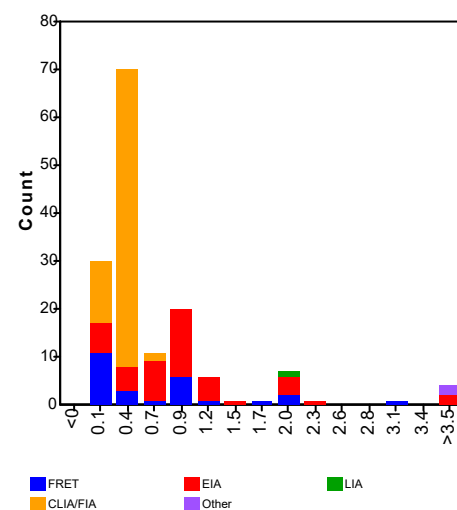
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	152	0.5	0.04	80.7	0.0 - 10.0	<1.0					
FRET	26	0.6	0.18	114.0	0.0 - 3.0	<1.0					
Technoclone Technofluor activity	18	0.6	0.18	105.1	0.0 - 1.9	<1.0					

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	152	0.5	0.04	80.7	0.0 - 10.0
FRET	26	0.6	0.18	114.0	0.0 - 3.0
Homemade	3	0.0			0.0 - 0.0
Immucor activity	2	1.5			1.0 - 1.9
Other	2	0.5			0.0 - 1.0
Sekisui Actifluor activity	1	3.0			-
Enzyme Immuno Assay	46	0.9	0.11	66.0	0.0 - 10.0
Other	1	2.0			-
Technoclone Technozym activity	44	0.9	0.11	64.8	0.0 - 10.0
Technoclone Technozym activity/antigen	1	1.0			-
Latex Immuno Assay	1	1.9			-
Homemade	1	1.9			-
CLIA/FIA	77	0.3	0.01	26.5	0.0 - 0.6
Other	1	0.3			-
Werfen Acustar activity	76	0.3	0.01	26.7	0.0 - 0.6
Other	2	7.1			7.0 - 7.2
Homemade	2	7.1			7.0 - 7.2



ADAMTS13 - I	ADAMTS13 Activity
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Sample No 25.52

Sample Details Plasma with an ADAMTS13 activity level between 10 and 20%

Prior Use None

Unit % or IU/dL

Expiry Date 30-November-2026

Homogeneity 4.6 %

Homogeneity Parameter ADAMTS13

For any method used for the measurement of this parameter with a **CV ≤ 15.3%** 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 199

Number of Responders 186

Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis:

904: 6.4 U/mL

6212: 0 U/mL

6239: 80%

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	3	3	13	188	2

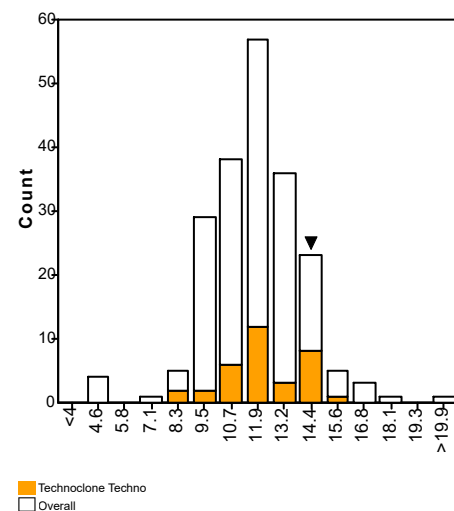
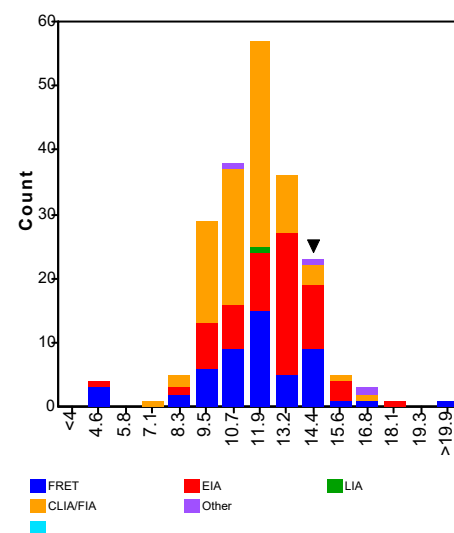
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	203	12	0.16	15.2	4 - 32	14.1	1.25				
FRET	52	12	0.35	16.7	4 - 32	14.1	1.09				
Technoclone Technofluor activity	34	12	0.36	13.7	9 - 16	14.1	1.09				

Other Reagents

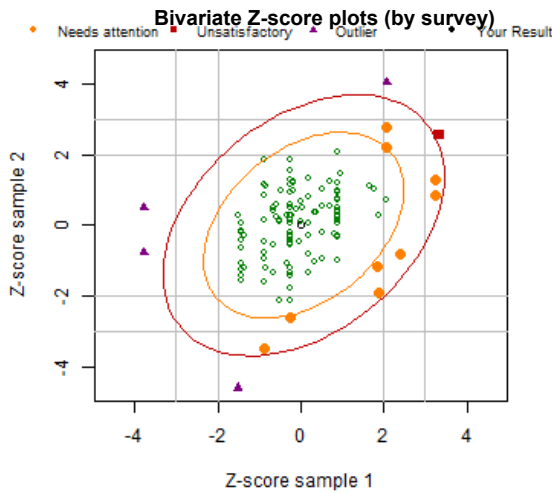
	n	assigned value	Uncert.	CV (%)	Range
Total Group	203	12	0.16	15.2	4 - 32
FRET	52	12	0.35	16.7	4 - 32
Homemade	12	10	1.36	37.8	4 - 14
Immucor activity	2	9.8			9.6 - 10.0
Other	3	13			10 - 32
Sekisui Actifluor activity	1	17			-
Enzyme Immuno Assay	61	13	0.30	14.8	4 - 18
Other	1	9.0			-
Technoclone Technozym activity	59	13	0.29	14.1	4 - 18
Technoclone Technozym activity/antigen	1	10			-
Latex Immuno Assay	1	12			-
Homemade	1	12			-
CLIA/FIA	86	11	0.19	12.5	8 - 17
Other	1	13			-
Werfen Acustar activity	85	11	0.19	12.5	8 - 17
Other	3	14			11 - 17
Homemade	2	12			11 - 14
Other	1	17			-



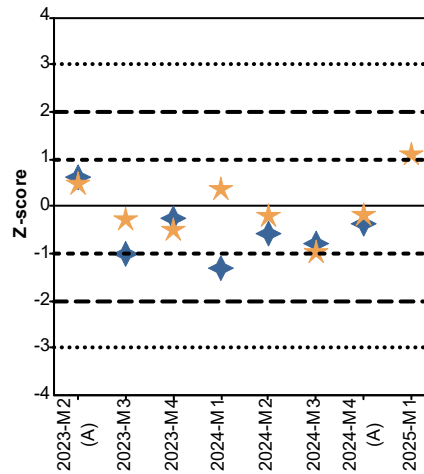
ADAMTS13 - I

ADAMTS13 Activity

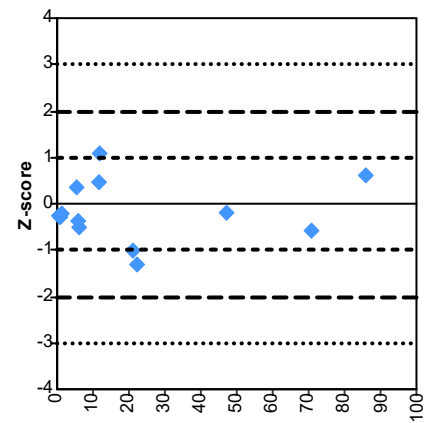
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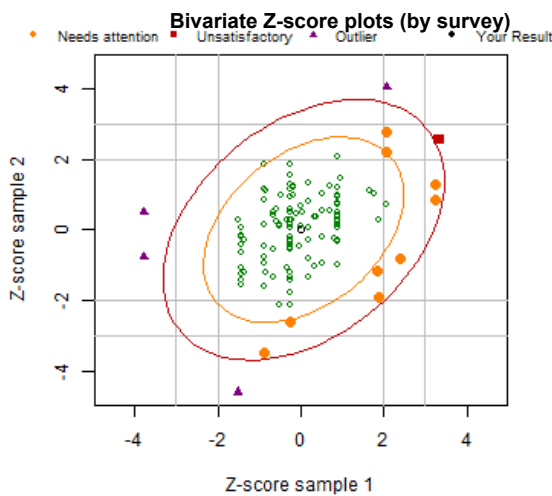
Z-score history (by survey)



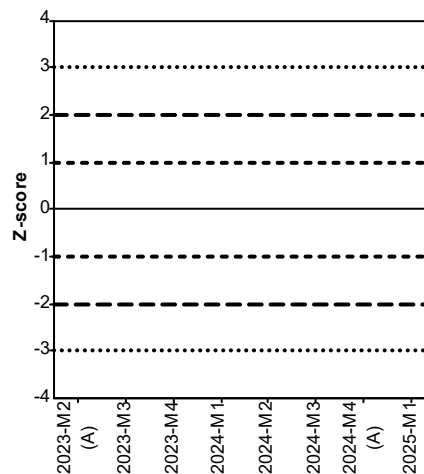
Z-score history (by consensus value)



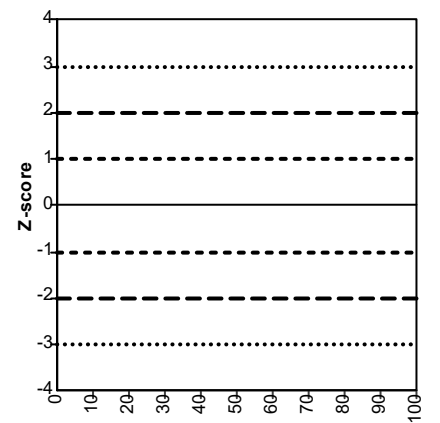
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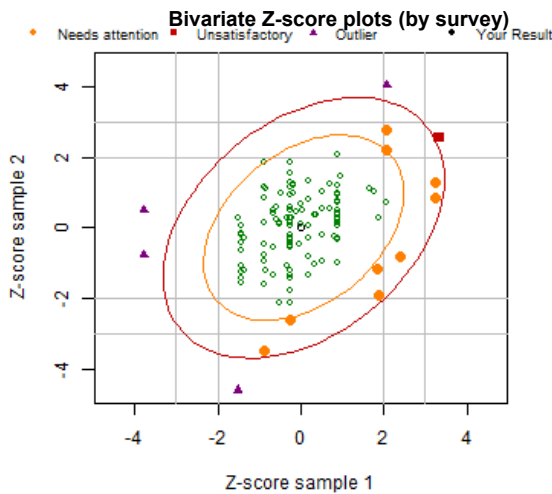
Z-score history (by survey)



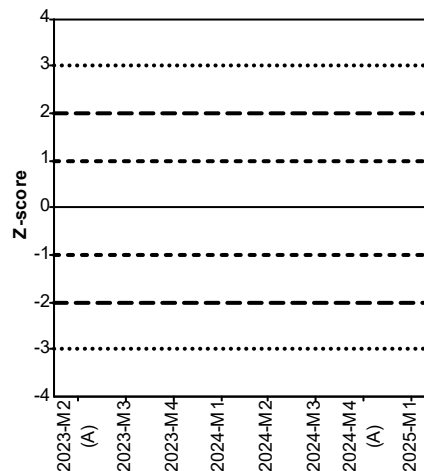
Z-score history (by consensus value)



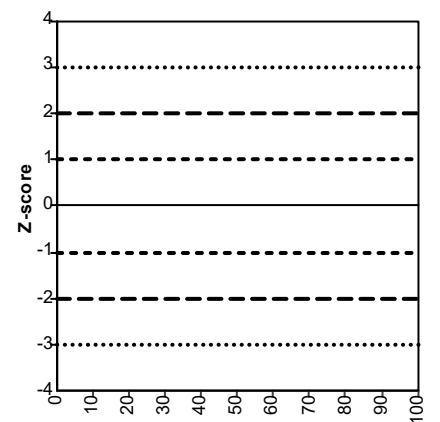
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

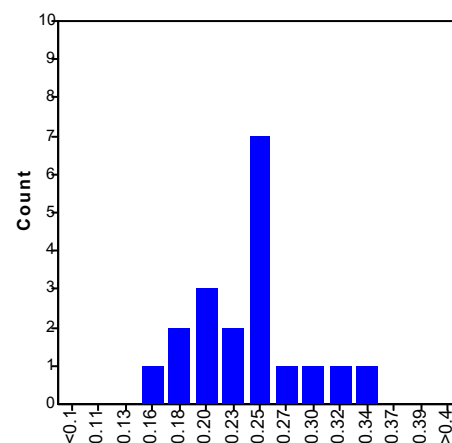
ADAMTS13 antigen

Sample No	25.51		
Sample Details	Plasma with an ADAMTS13 activity level <5%		
Prior Use	None		
Unit	IU/mL		
Expiry Date	30-November-2026		
Homogeneity	27.0 %	Homogeneity Parameter	ADAMTS13
	For any method used for the measurement of this parameter with a $CV \leq 90.0\%$ 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	199		
Number of Responders	24	Response Rate	12 %
Comments	The following participant reported a result in $\mu\text{g/mL}$ which was excluded from the statistical analysis: 216 : 0.256 $\mu\text{g/mL}$		
	The following participants reported deviating results which were excluded from the statistical analysis: 215: 0.411% 950: 23.373 U/mL 1511: 1.4%		

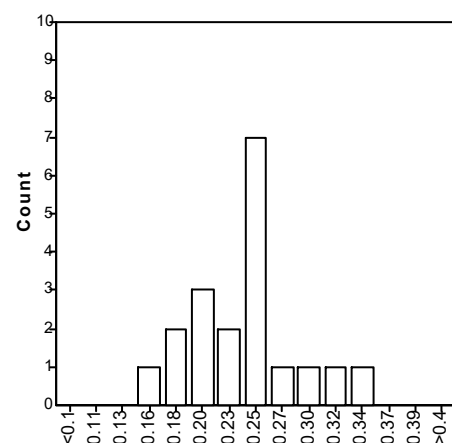
Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	0	0	1	22	1

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	19	0.24	0.01	19.1	0.15 - 0.34
Other	1	0.26			-
Sekisui Imubind antigen	1	0.15			-
Technozym Technozym activity/antigen	2	0.29			0.24 - 0.34
Technozym Technozym antigen	15	0.24	0.01	17.2	0.18 - 0.33



■ EIA



□ Overall

ADAMTS13 - I

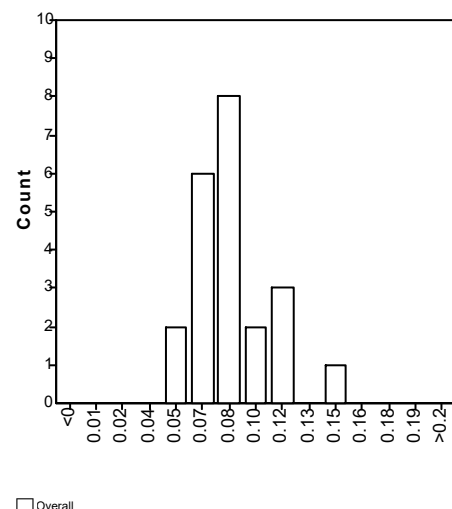
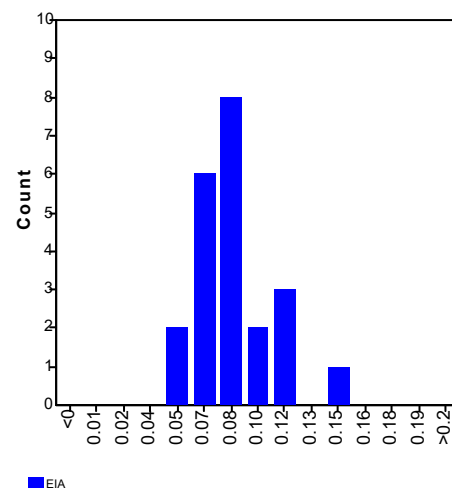
ADAMTS13 antigen

Sample No	25.52		
Sample Details	Plasma with an ADAMTS13 activity level between 10 and 20%		
Prior Use	None		
Unit	IU/mL		
Expiry Date	30-November-2026		
Homogeneity	4.6 %	Homogeneity Parameter	ADAMTS13
	For any method used for the measurement of this parameter with a $CV \leq 15.3\%$ 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	199		
Number of Responders	24	Response Rate	12 %
Comments	The following participant reported a result in $\mu\text{g/mL}$ which was excluded from the statistical analysis: 216: 0.069 $\mu\text{g/mL}$		
	The following participant reported a deviating result which was excluded from the statistical analysis: 950: 7.716 U/mL		

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	0	0	0	23	1

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	22	0.08	0.01	27.3	0.05 - 0.14
Homemade	1	0.07			-
Other	1	0.08			-
Sekisui Imubind antigen	1	0.12			-
Technozym Technozym activity/antigen	4	0.09			0.06 - 0.12
Technozym Technozym antigen	15	0.08	0.01	20.9	0.05 - 0.14



ADAMTS13 - I

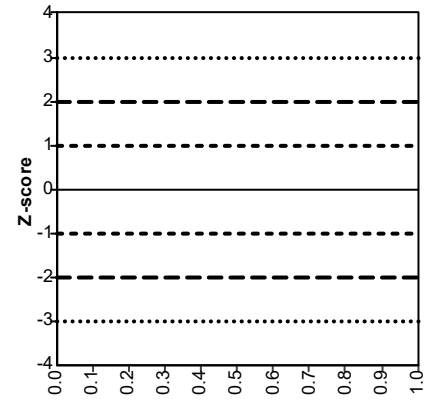
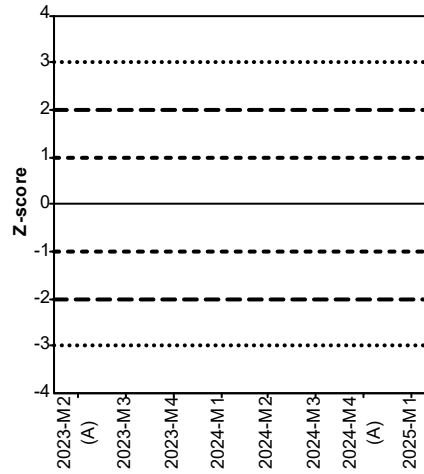
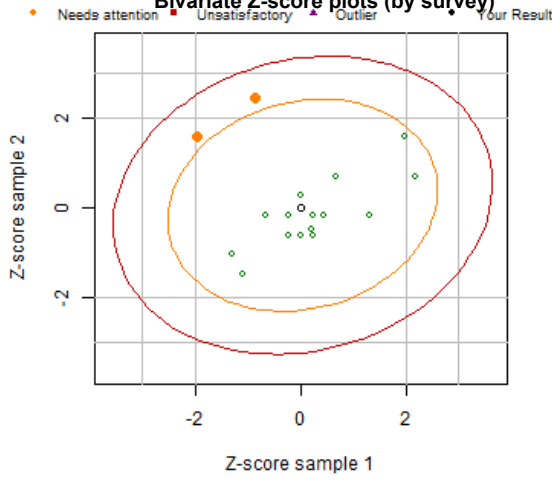
ADAMTS13 antigen

Instrument ID

Bivariate Z-score plots (by survey)

Z-score history (by survey)

Z-score history (by consensus value)

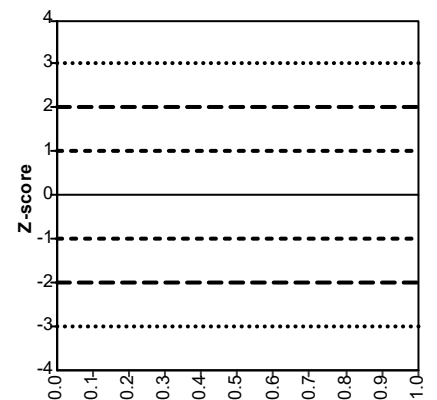
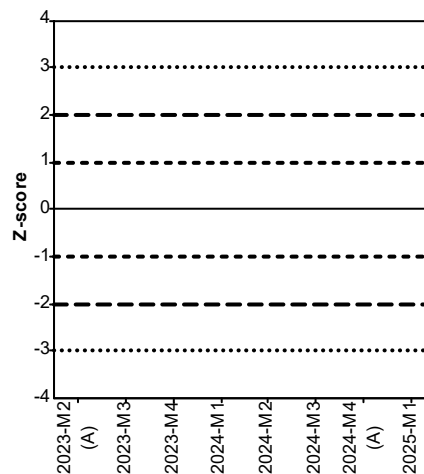
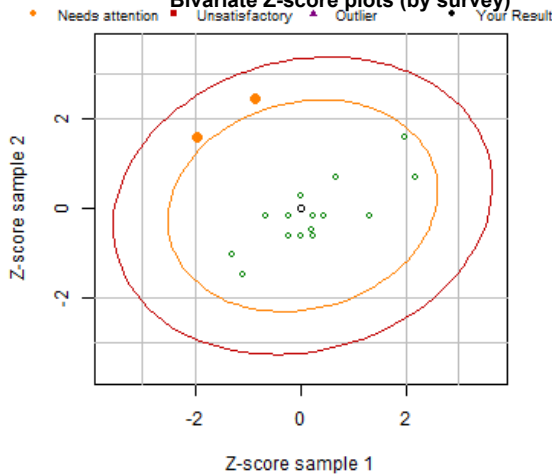


Instrument ID

Bivariate Z-score plots (by survey)

Z-score history (by survey)

Z-score history (by consensus value)



Instrument ID

Bivariate Z-score plots (by survey)

Z-score history (by survey)

Z-score history (by consensus value)

