

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-M4

Main

Labcode 1492

Date of Issue : 14-January-2025

Survey : 2024-M4

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

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 **March 6th, 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 actual Survey Manual can be downloaded by going to the "Participant Area" of the ECAT website, login and go to the option "View Documents".

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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 ≥ 3)
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
ADAMTS13 - I	ADAMTS13 Activity	24.216	1	-0.73	-0.37	-0.37	
		24.217	1	-0.15	-0.19	-0.19	

ADAMTS13 - I **ADAMTS13 Activity**

Sample No	24.216		
Sample Details	Plasma with an ADAMTS13 activity level <5%		
Prior Use	None		
Unit	% or IU/dL		
Expiry Date	31-July-2026		
Homogeneity	0.0 %	Homogeneity Parameter	ADAMTS13
Number of Participants	191		
Number of Responders	173	Response Rate	91 %
Comments	The results of 2 participants (labcodes 904 and 9045) were excluded because they reported the results with an incorrect units (IU/mL instead of %).		

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	0	0	0	192	3

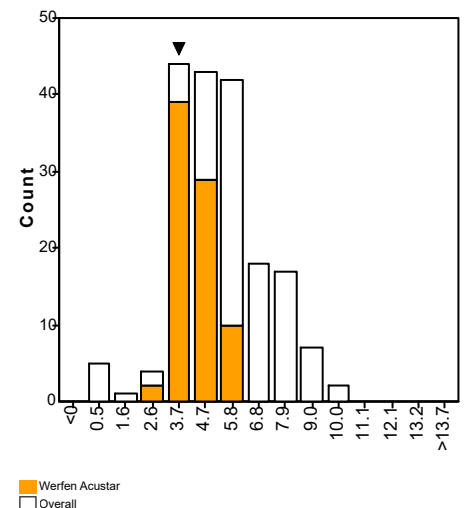
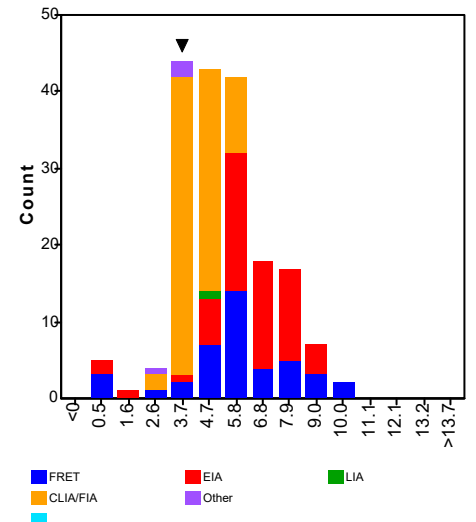
Your Classification: Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	183	5.3	0.15	31.0	0.0 - 10.0	4.1	-0.73				
CLIA/FIA	80	4.4	0.10	15.9	2.6 - 6.1	4.1	-0.37				
Werfen Acustar activity	80	4.4	0.10	15.9	2.6 - 6.1	4.1	-0.37				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	183	5.3	0.15	31.0	0.0 - 10.0
FRET	41	6.0	0.38	32.4	0.0 - 10.0
Homemade	8	5.0			0.0 - 8.0
Immucor activity	3	8.6			7.9 - 9.0
Other	2	5.6			3.2 - 8.0
Sekisui Actifluor activity	2	5.5			1.0 - 10.0
Technoclone Technofluor activity	26	5.9	0.27	18.6	3.6 - 10.0
Enzyme Immuno Assay	58	6.6	0.22	20.3	0.0 - 9.2
Other	1	8.0			-
Technoclone Technozym activity	56	6.6	0.22	19.9	0.0 - 9.2
Technoclone Technozym activity/antigen	1	5.0			-
Latex Immuno Assay	1	4.7			-
Homemade	1	4.7			-
CLIA/FIA	80	4.4	0.10	15.9	2.6 - 6.1
Other	3	3.5			3.0 - 4.2
Homemade	2	3.6			3.0 - 4.2
Other	1	3.5			-



ADAMTS13 - I	ADAMTS13 Activity
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Sample No 24.217
Sample Details Abnormal Coagulation Control Plasma
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2025
Homogeneity 1.0 % **Homogeneity Parameter** APTT

For any method used for the measurement of this parameter with a CV ≤ 3.3% 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 191
Number of Responders 173 **Response Rate** 91 %

Comments The results of 2 participants (**labcodes 904 and 9045**) were excluded because they reported the results with an incorrect units (IU/mL instead of %).

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	60	20	37	75	3

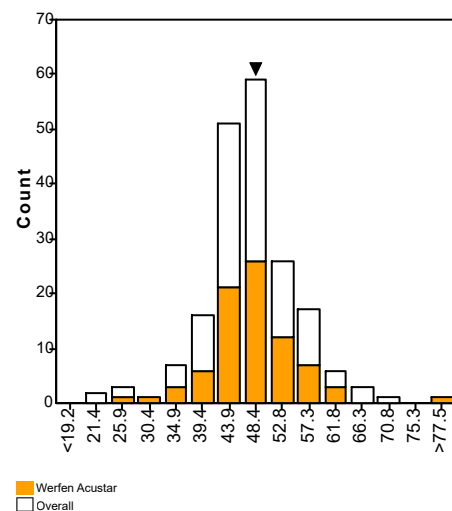
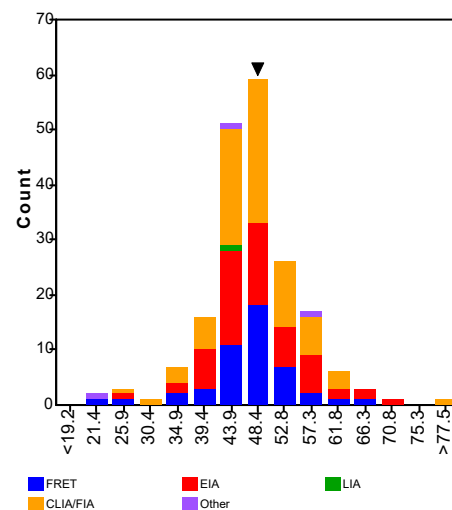
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	193	48	0.56	12.9	21 - 78	46.8	-0.15				
CLIA/FIA	81	48	0.79	11.9	26 - 78	46.8	-0.19				
Werfen Acustar activity	81	48	0.79	11.9	26 - 78	46.8	-0.19				

Other Reagents

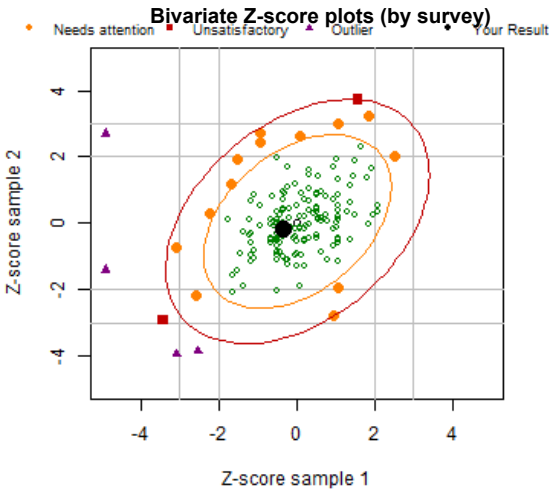
	n	assigned value	Uncert.	CV (%)	Range
Total Group	193	48	0.56	12.9	21 - 78
FRET	47	47	1.02	11.8	21 - 68
Homemade	13	48	3.90	23.6	25 - 64
Immucor activity	3	53			47 - 68
Other	3	42			21 - 52
Sekisui Actifluor activity	2	42			35 - 49
Technoclone Technofluor activity	26	47	0.79	6.9	41 - 52
Enzyme Immuno Assay	61	48	1.17	15.1	27 - 72
Homemade	1	50			-
Other	1	49			-
Technoclone Technozym activity	58	48	1.22	15.3	27 - 72
Technoclone Technozym activity/antigen	1	40			-
Latex Immuno Assay	1	43			-
Homemade	1	43			-
CLIA/FIA	81	48	0.79	11.9	26 - 78
Other	3	45			23 - 57
Homemade	2	40			23 - 57
Other	1	45			-



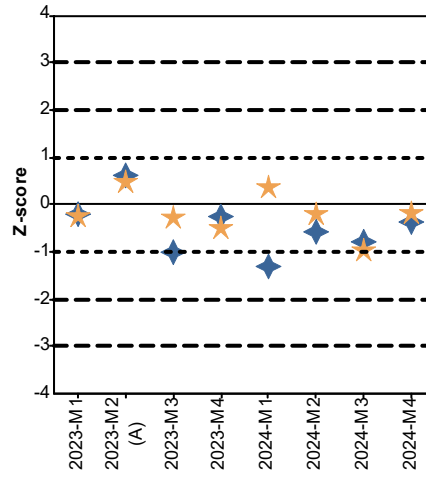
ADAMTS13 - I

ADAMTS13 Activity

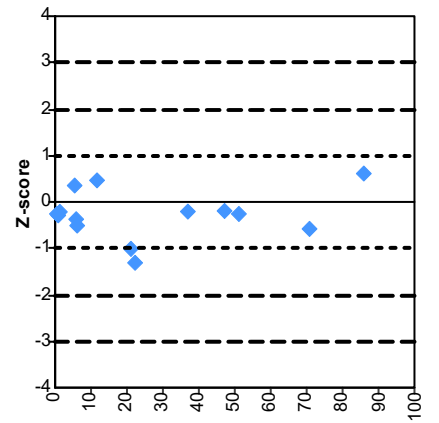
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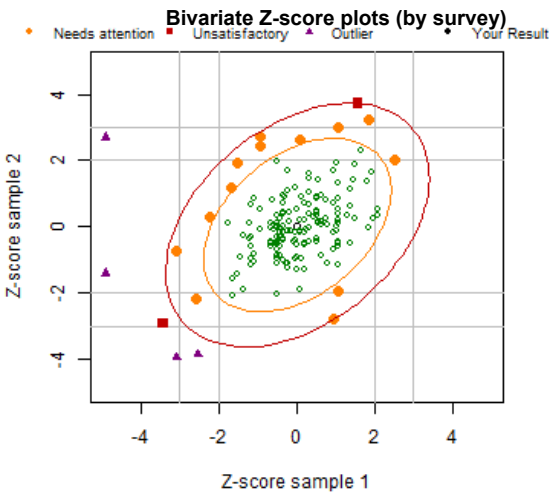
Z-score history (by survey)



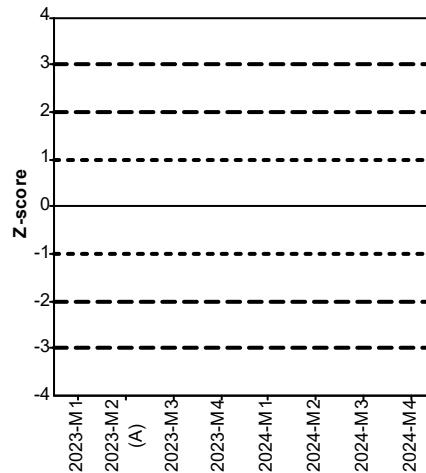
Z-score history (by consensus value)



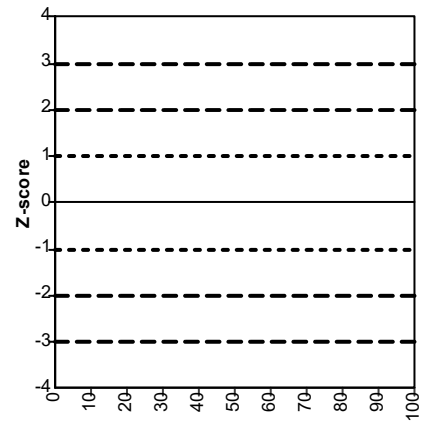
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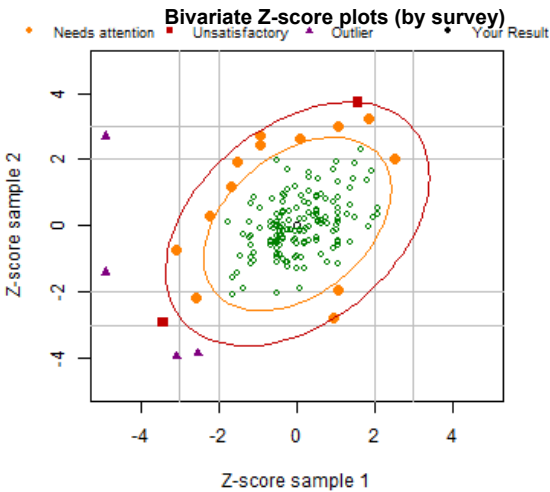
Z-score history (by survey)



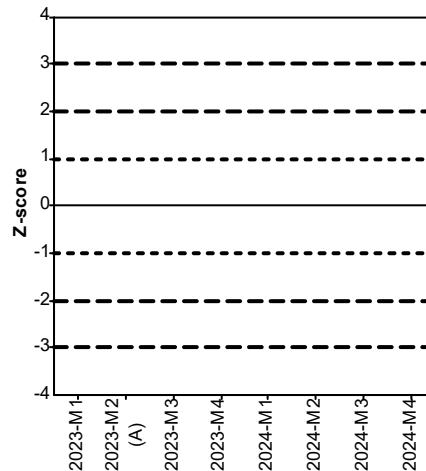
Z-score history (by consensus value)



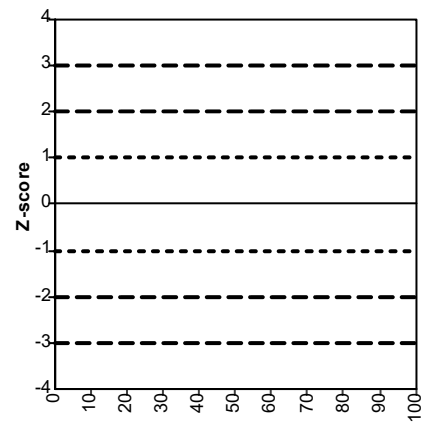
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



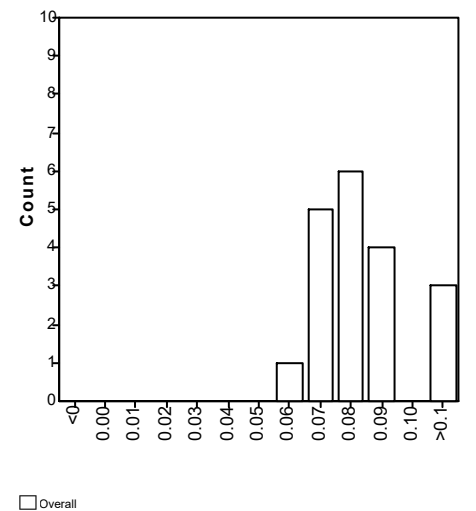
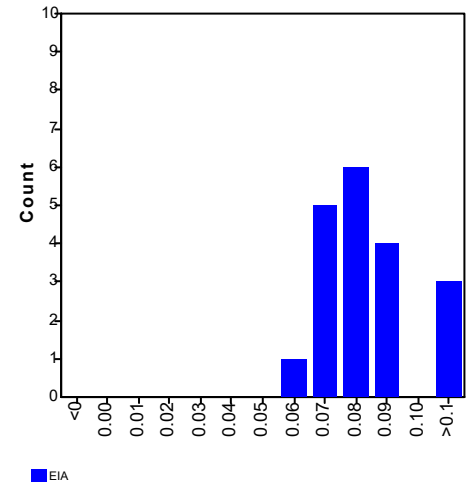
ADAMTS13 - I **ADAMTS13 antigen**

Sample No 24.216
Sample Details Plasma with an ADAMTS13 activity level <5%
Prior Use None
Unit IU/mL
Expiry Date 31-July-2026
Homogeneity 0.0 % **Homogeneity Parameter** ADAMTS13
Number of Participants 191
Number of Responders 21 **Response Rate** 11 %
Comments The results of 2 participants (**labcodes 215 and 950**) were excluded because they reported the results with an incorrect units (IU/mL instead of %).

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

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	19	0.08	0.00	17.8	0.06 - 0.13
Homemade	1	0.09			-
Sekisui Imubind antigen	1	0.07			-
Technozym Technozym activity/antigen	2	0.10			0.07 - 0.13
Technozym Technozym antigen	15	0.08	0.00	15.3	0.06 - 0.12



ADAMTS13 - I

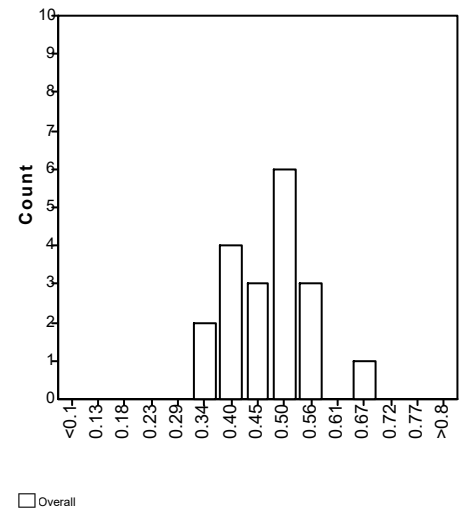
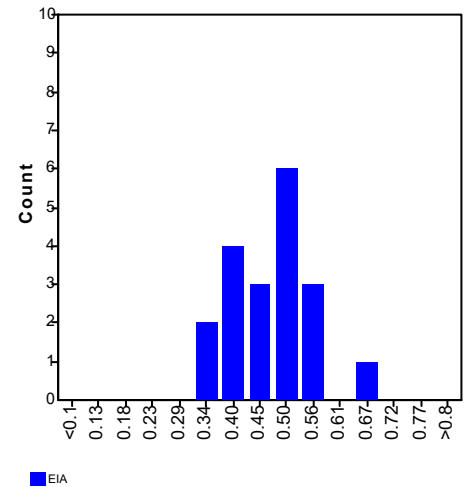
ADAMTS13 antigen

Sample No 24.217
Sample Details Abnormal Coagulation Control Plasma
Prior Use None
Unit IU/mL
Expiry Date 31-December-2025
Homogeneity 1.0 % **Homogeneity Parameter** APTT
 For any method used for the measurement of this parameter with a $CV \leq 3.3\%$ 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 191
Number of Responders 21 **Response Rate** 11 %
Comments The results of 2 participants (**labcodes 215 and 950**) were excluded because they reported the results with an incorrect units (IU/mL instead of %).

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	12	4	4	0	1

Other Reagents

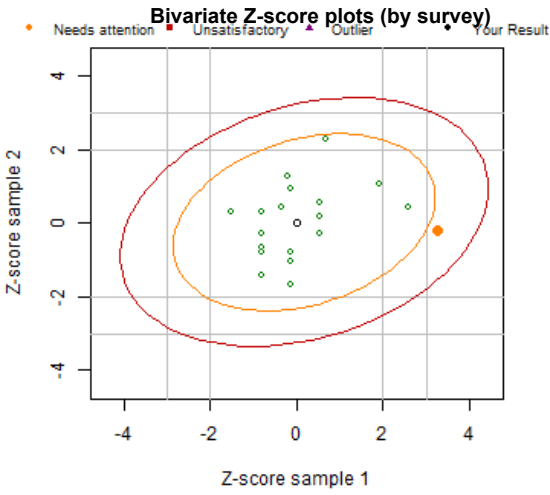
	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	19	0.47	0.02	17.1	0.34 - 0.66
Homemade	1	0.66			-
Sekisui Imubind antigen	1	0.50			-
Technozym Technozym activity/antigen	2	0.41			0.36 - 0.46
Technozym Technozym antigen	15	0.47	0.02	15.9	0.34 - 0.58



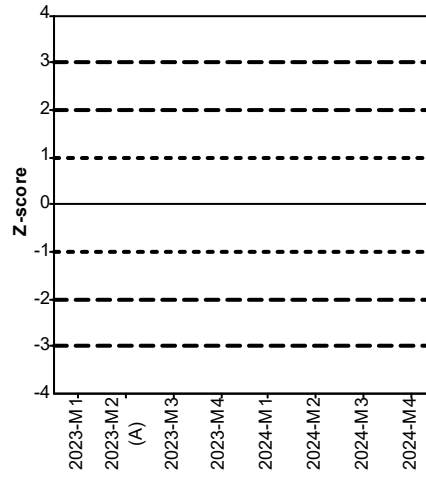
ADAMTS13 - I

ADAMTS13 antigen

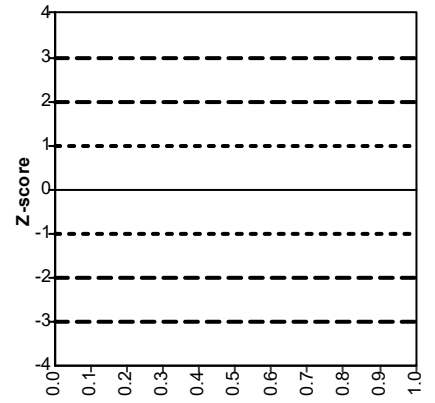
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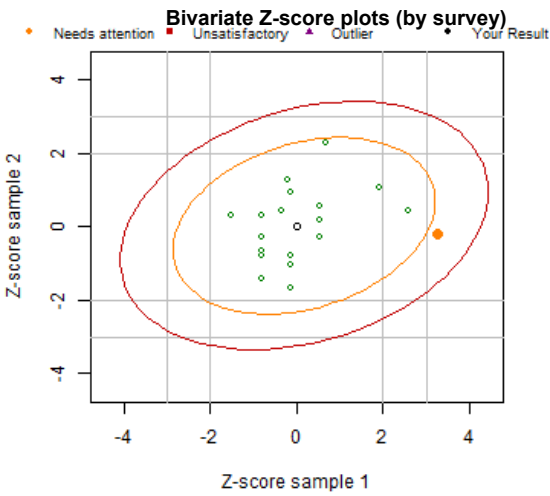
Z-score history (by survey)



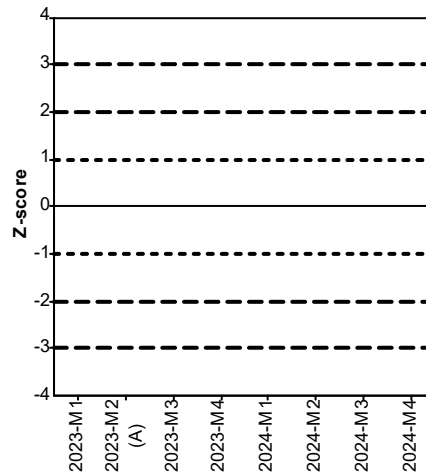
Z-score history (by consensus value)



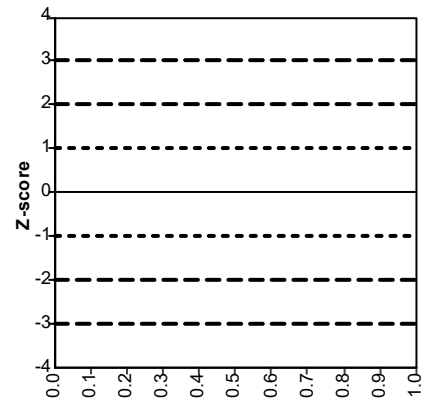
Instrument ID



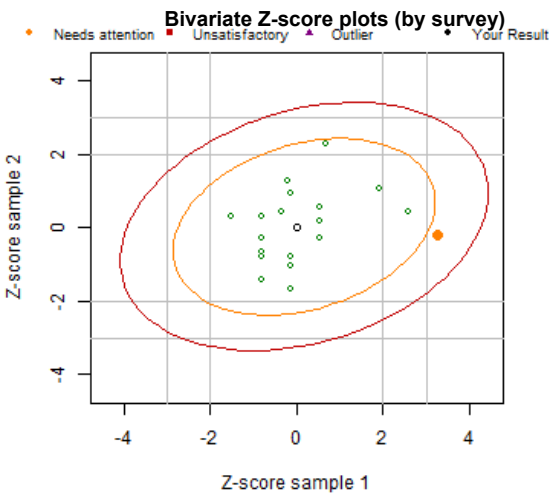
Z-score history (by survey)



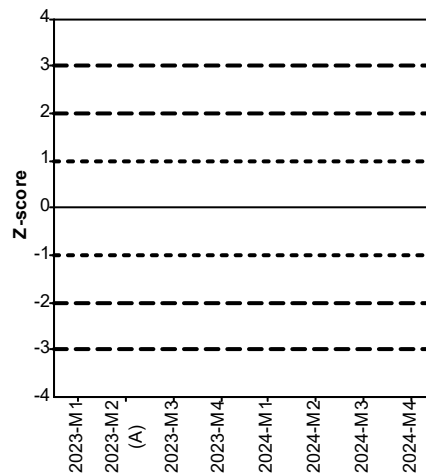
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

