ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2023-M4
Main
Labcode 1492

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Date of Issue : 05-januari-2024

Survey : 2023-M4

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 **March 5th, 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: 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.

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OVERVIEW Z-SCORES

UV:Satisfactory (-2 ≤ Z-score ≤ 2)

UV: Need attention (-3 < Z-score < -2 or 2 < Z-score < 3)

UV:Unsatisfactory (Z-score ≤ -3 or ≥ 3)
BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivarate Analysis
ADAMTS13 - I	ADAMTS13 Activty	23.197	1	-0.41	-0.25	-0.28	
		23.198	1	-0.68	-0.50	-0.45	

ADAMTS13 - I

ADAMTS13 Activity

Sample No 23.197
Sample Details Plasma with an ADAMTS13 activity level < 1%
Prior Use 2023-M3
Unit % or IU/dL
Expiry Date 30-april-2025
Homogeneity 62.6 % **Homogeneity Parameter** ADAMTS13
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 167
Number of Responders 153 **Response Rate** 92 %
Comments The following participants reported deviating results which were excluded in the statistical evaluation:
1508 : 9%
1607 : 9.1%

For the most frequently used reagents (n >= 10) the results of sample 23.197 are comparable to those of sample 23.153 in survey 2023-M3.

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 affect the interlaboratory variation results for this sample.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	0	1	168	1

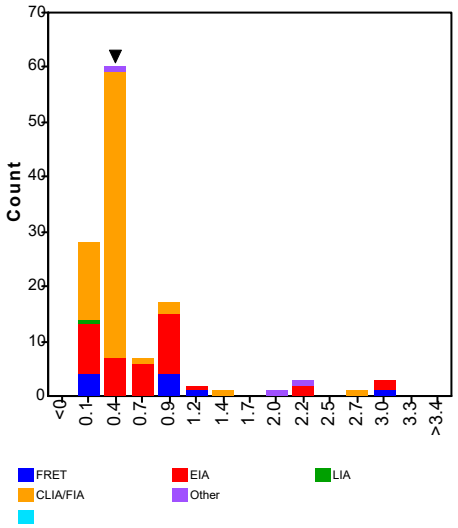
Your Classification Abnormal

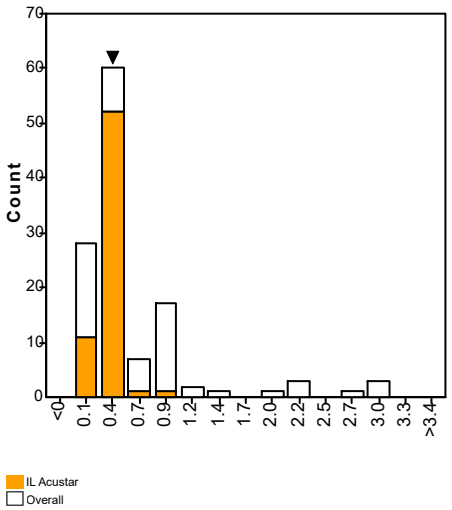
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	123	0.5	0.04	82.8	0.0 - 3.0	0.3	-0.41				
CLIA/FIA	71	0.3	0.02	32.7	0.0 - 2.7	0.3	-0.25				
IL Acustar ADAMTS13 activity	65	0.3	0.01	28.0	0.0 - 1.0	0.3	-0.28				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	123	0.5	0.04	82.8	0.0 - 3.0
FRET	10	0.6	0.27	105.6	0.0 - 3.0
Homemade	2	0.6			0.0 - 1.1
Immucor ADAMTS13 activity	1	0.9			-
Other	6	0.4			0.0 - 1.0
Sekisui Actifluor ADAMTS13 activity	1	3.0			-
Enzyme Immuno Assay	38	0.7	0.11	81.1	0.0 - 3.0
Homemade	1	0.0			-
Technoclone ADAMTS13 acitivity	36	0.7	0.11	75.0	0.0 - 3.0
Technoclone ADAMTS13 activity/antigen	1	0.0			-
Latex Immuno Assay	1	0.0			-
Homemade	1	0.0			-
CLIA/FIA	71	0.3	0.02	32.7	0.0 - 2.7
Technoclone Technofluor ADAMTS13 ac	6	0.5			0.0 - 2.7
Other	3	2.0			0.5 - 2.3
Homemade	2	2.2			2.0 - 2.3
Other	1	0.5			-





ADAMTS13 - I

ADAMTS13 Activity

Sample No	23.198		
Sample Details	Plasma with an ADAMTS13 activity level between 5 and 10%		
Prior Use	None		
Unit	% or IU/dL		
Expiry Date	31-augustus-2025		
Homogeneity	0.0 %	**Homogeneity Parameter**	ADAMTS13
Number of Participants	167		
Number of Responders	153	**Response Rate**	92 %

Comments The following participants reported deviating results which were excluded in the statistical evaluation:

350 : 0.059%
506 : 0.1%
6212 : 0%
9151 : 0.9%

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	1	4	163	1

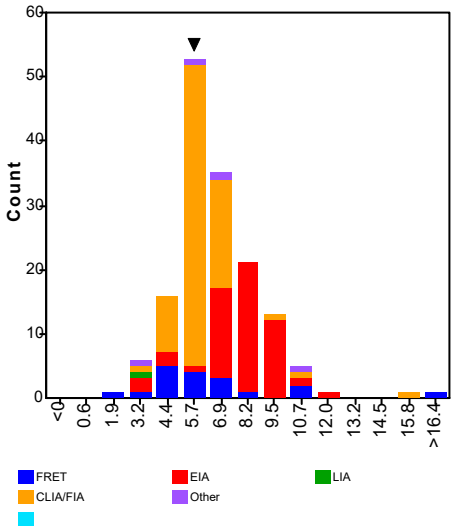
Your Classification Abnormal

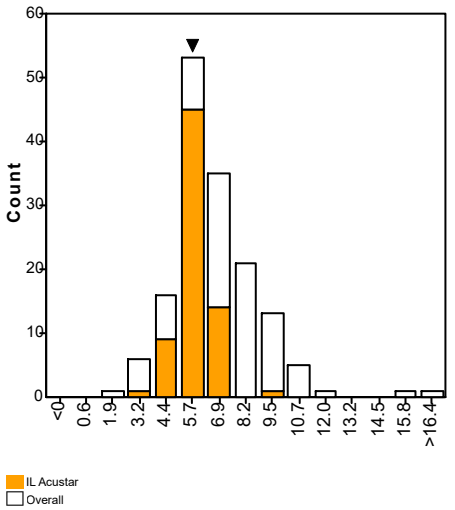
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	153	6.6	0.17	25.0	2.0 - 16.8	5.5	-0.68				
CLIA/FIA	77	5.9	0.11	13.3	3.5 - 15.9	5.5	-0.50				
IL Acustar ADAMTS13 activity	70	5.8	0.11	12.2	3.5 - 10.0	5.5	-0.45				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	153	6.6	0.17	25.0	2.0 - 16.8
FRET	18	6.2	0.75	40.6	2.0 - 16.8
Homemade	6	6.5			2.0 - 11.0
Immucor ADAMTS13 activity	4	9.1			3.7 - 16.8
Other	7	5.0			4.0 - 6.1
Sekisui Actifluor ADAMTS13 activity	1	7.0			-
Enzyme Immuno Assay	53	7.9	0.21	15.4	3.0 - 12.4
Homemade	1	12			-
Other	1	9.0			-
Technoclone ADAMTS13 acitivity	50	7.9	0.20	14.5	3.0 - 10.8
Technoclone ADAMTS13 activity/antigen	1	3.0			-
Latex Immuno Assay	1	3.2			-
Homemade	1	3.2			-
CLIA/FIA	77	5.9	0.11	13.3	3.5 - 15.9
Technoclone Technofluor ADAMTS13 ac	7	7.0			5.1 - 15.9
Other	4	6.6			3.0 - 10.4
Homemade	2	6.7			3.0 - 10.4
Other	2	6.6			6.2 - 7.0



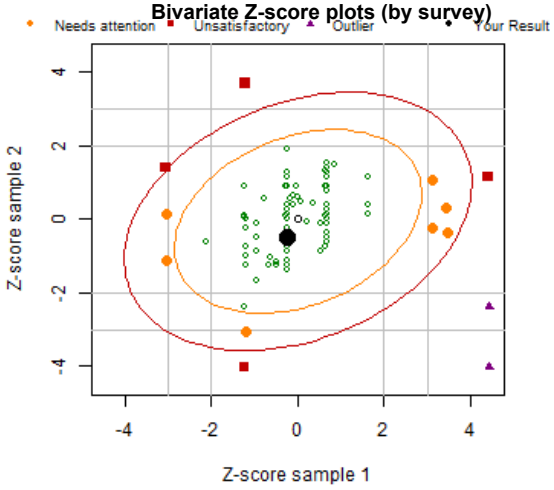


ADAMTS13 - I

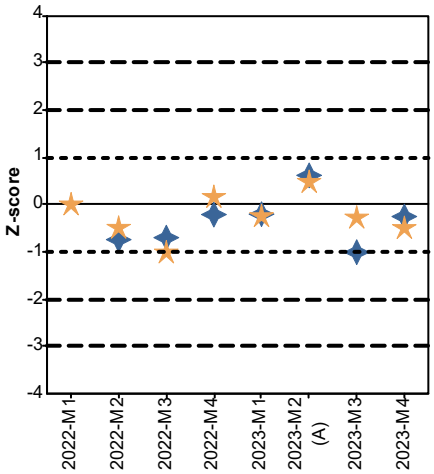
ADAMTS13 Activity

Instrument ID	

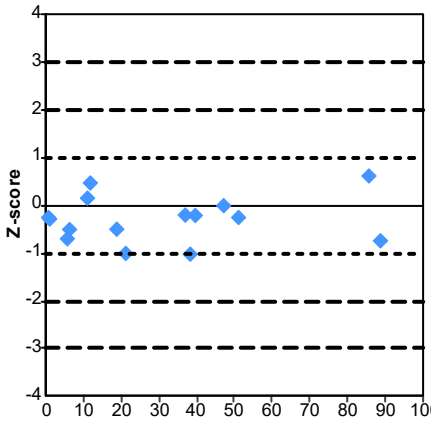
Bivariate Z-score plots (by survey)



Z-score history (by survey)

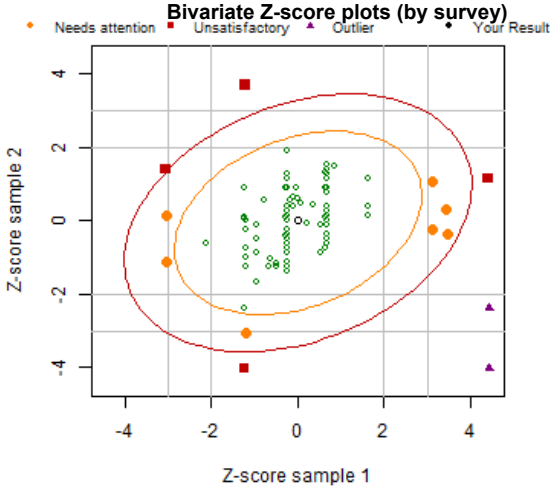


Z-score history (by consensus value)

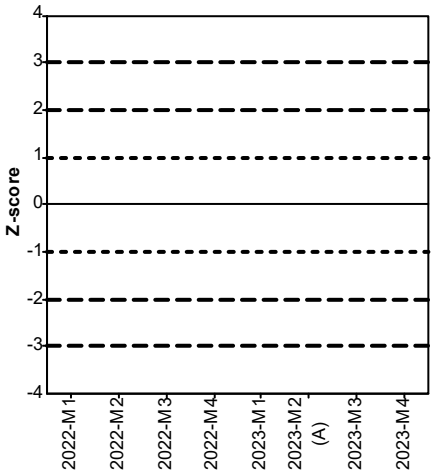


Instrument ID	

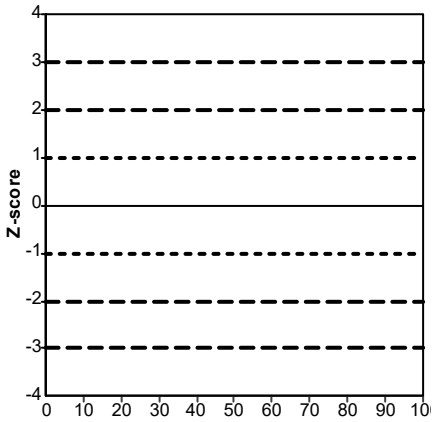
Bivariate Z-score plots (by survey)



Z-score history (by survey)

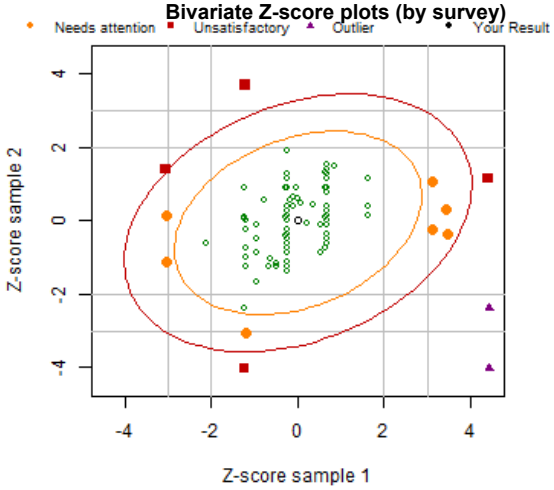


Z-score history (by consensus value)

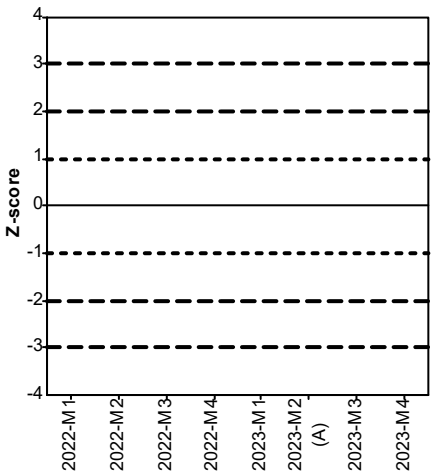


Instrument ID	

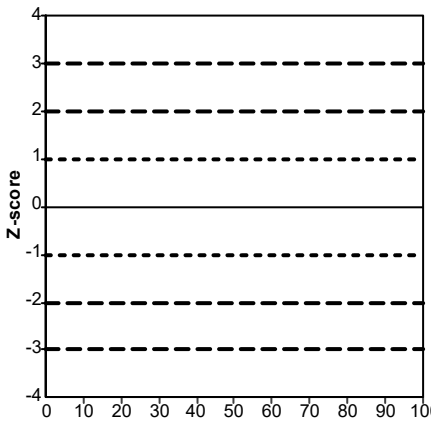
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

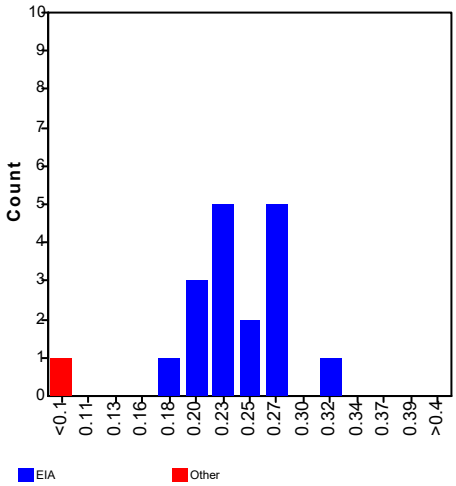
ADAMTS13 antigen

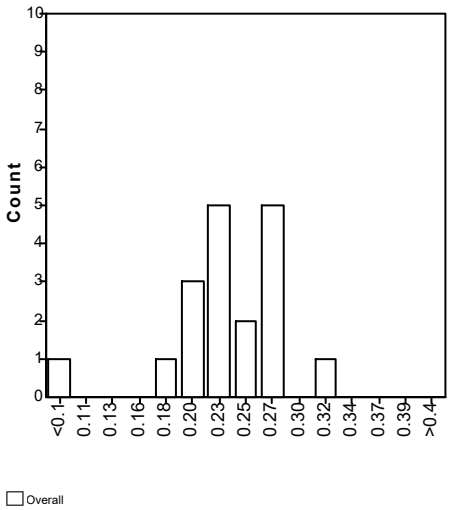
Sample No	23.197
Sample Details	Plasma with an ADAMTS13 activity level < 1%
Prior Use	2023-M3
Unit	IU/mL
Expiry Date	30-april-2025
Homogeneity	62.6 % **Homogeneity Parameter** ADAMTS13
	For any method used for the measurement of this parameter with a **CV ≤ 208.7%** the criterion for homogeneity could 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	167
Number of Responders	19 **Response Rate** 11 %
Comments	One participant (labcode **1086**) selected the wrong unit when submitting the result. This result was excluded in the statistical evaluation. For the most frequently used reagents (n >= 10) the results of sample 23.197 are comparable to those of sample 23.153 in survey 2023-M3. 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 affect the interlaboratory variation results for this sample.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	1	0	18	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	18	0.24	0.01	18.0	0.06 - 0.32
Enzyme Immuno Assay	17	0.24	0.01	16.5	0.19 - 0.32
Technozym ADAMTS13 antigen	17	0.24	0.01	16.5	0.19 - 0.32
Other	1	0.06			-
Homemade	1	0.06			-





ADAMTS13 - I

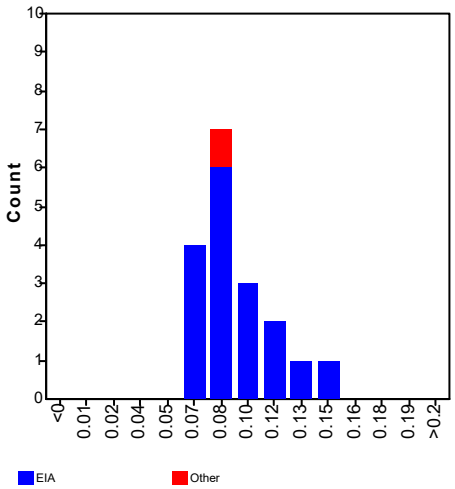
ADAMTS13 antigen

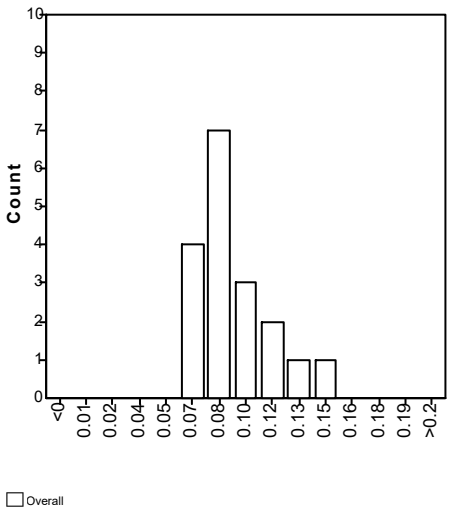
Sample No	23.198		
Sample Details	Plasma with an ADAMTS13 activity level between 5 and 10%		
Prior Use	None		
Unit	IU/mL		
Expiry Date	31-augustus-2025		
Homogeneity	0.0 %	**Homogeneity Parameter**	ADAMTS13
Number of Participants	167		
Number of Responders	19	**Response Rate**	11 %
Comments	One participant (labcode **1086**) selected the wrong unit when submitting the result. This result was excluded in the statistical evaluation.		

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

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	18	0.09	0.01	22.8	0.07 - 0.14
Enzyme Immuno Assay	17	0.09	0.01	23.9	0.07 - 0.14
Technozym ADAMTS13 antigen	17	0.09	0.01	23.9	0.07 - 0.14
Other	1	0.09			-
Homemade	1	0.09			-



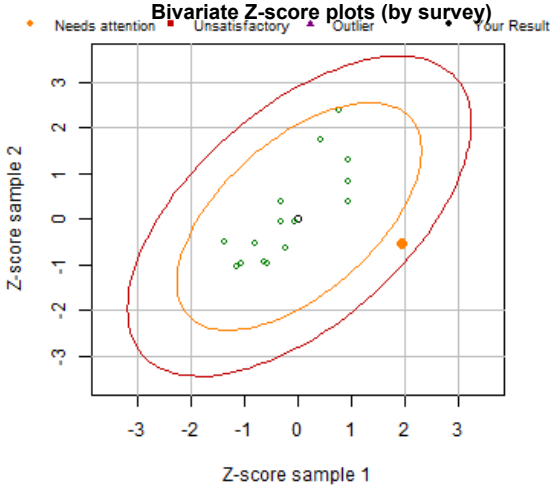


ADAMTS13 - I

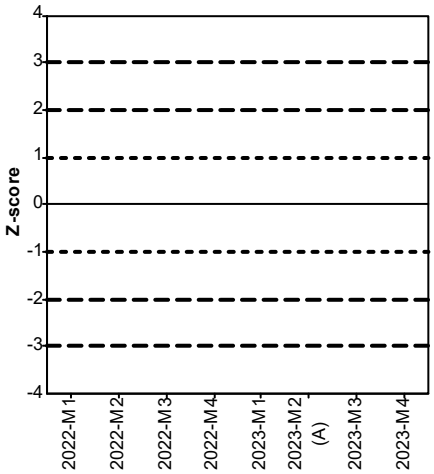
ADAMTS13 antigen

Instrument ID	

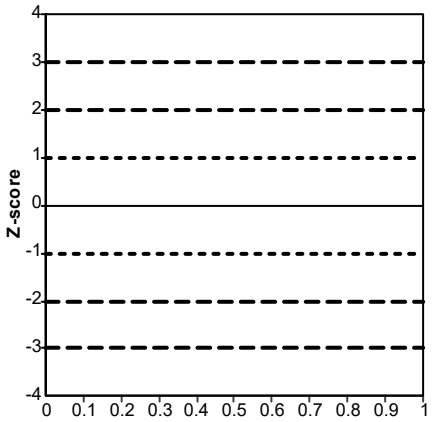
Bivariate Z-score plots (by survey)



Z-score history (by survey)

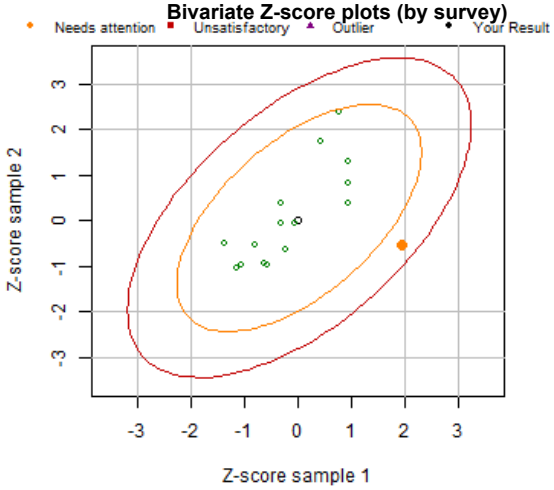


Z-score history (by consensus value)



Instrument ID	

Bivariate Z-score plots (by survey)



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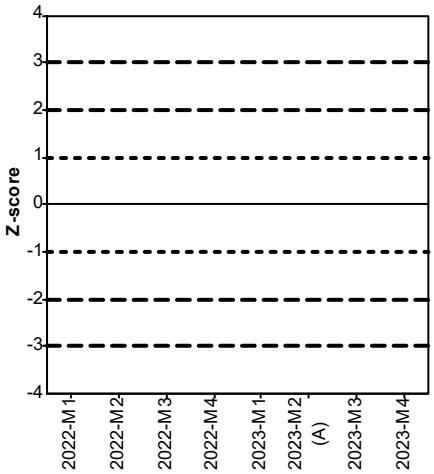
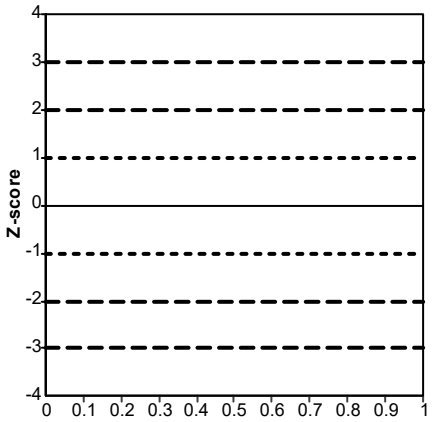
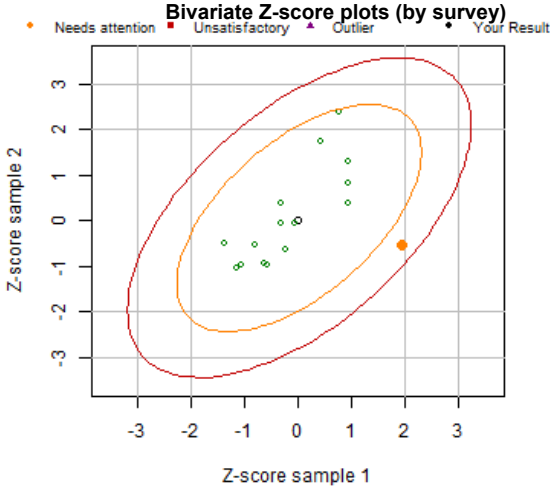


Z-score history (by consensus value)

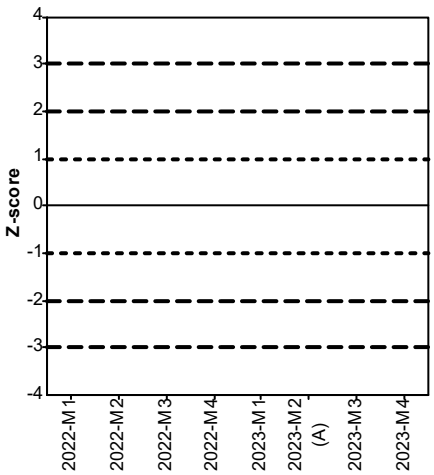
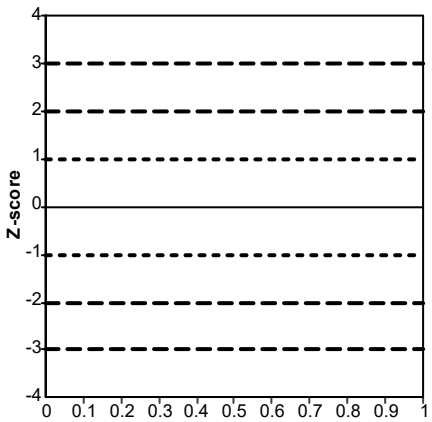


Instrument ID	

Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)