

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-M1

Main

Labcode 1492

Date of Issue : 07-mei-2024

Survey : 2024-M1

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 **June 21st, 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".

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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	24.51	1	-1.38	-1.31	-1.31	
		24.52	1	-0.40	0.36	0.36	

ADAMTS13 - I	ADAMTS13 Activity
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Sample No 24.51
Sample Details Plasma with an ADAMTS13 activity level between 20 and 30%
Prior Use None
Unit % or IU/dL
Expiry Date 31-oktober-2025
Homogeneity 0.8 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a $CV \leq 2.7\%$ 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 179
Number of Responders 163 **Response Rate** 91 %

Comments All participants who used the equipment Technoclone Ceveron for their ADAMTS13 activity measurement and did not specify a method or selected the wrong Technoclone method, were adapted to the Technoclone Technofluor ADAMTS13 activity method. Please select the correct method in the next survey.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	6	3	10	162	3

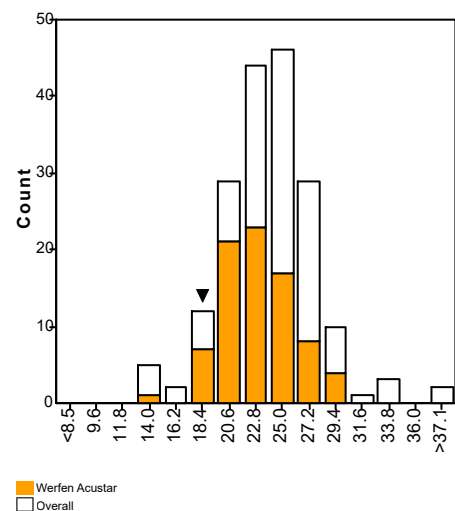
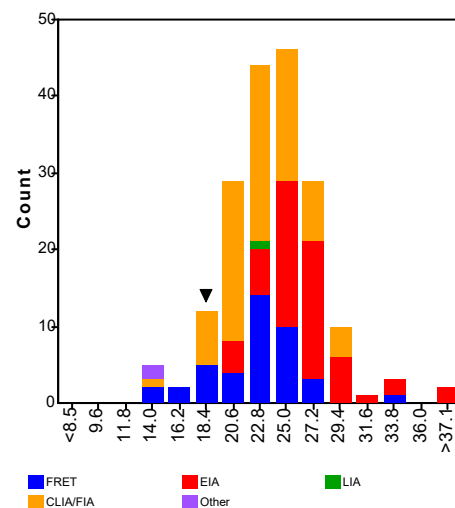
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result		your result		your result	
						z-score	z-score	z-score	z-score		
Total Group	183	24	0.32	14.8	13 - 41	18.9	-1.38				
CLIA/FIA	81	23	0.42	13.2	14 - 29	18.9	-1.31				
Werfen Acustar activity	81	23	0.42	13.2	14 - 29	18.9	-1.31				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	183	24	0.32	14.8	13 - 41
FRET	41	22	0.67	15.5	15 - 33
Homemade	11	21	1.89	23.5	15 - 27
Immucor activity	4	27			22 - 33
Other	3	19			16 - 20
Sekisui Actifluor activity	2	25			24 - 25
Technoclone Technofluor activity	21	22	0.56	9.2	18 - 26
Enzyme Immuno Assay	58	26	0.45	10.4	20 - 41
Homemade	1	23			-
Other	1	26			-
Technoclone Technozym activity	56	26	0.45	10.3	20 - 41
Latex Immuno Assay	1	23			-
Homemade	1	23			-
CLIA/FIA	81	23	0.42	13.2	14 - 29
Other	2	14			13 - 14
Homemade	2	14			13 - 14



ADAMTS13 - I	ADAMTS13 Activity
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Sample No 24.52
Sample Details Plasma with an ADAMTS13 activity level between 5 and 10%
Prior Use None
Unit % or IU/dL
Expiry Date 31-oktober-2025
Homogeneity 5.9 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 19.7%** 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 179
Number of Responders 163 **Response Rate** 91 %

Comments All participants who used the equipment Technoclone Ceveron for their ADAMTS13 activity measurement and did not specify a method or selected the wrong Technoclone method, were adapted to the Technoclone Technofluor ADAMTS13 activity method. Please select the correct method in the next survey.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	1	0	1	179	3

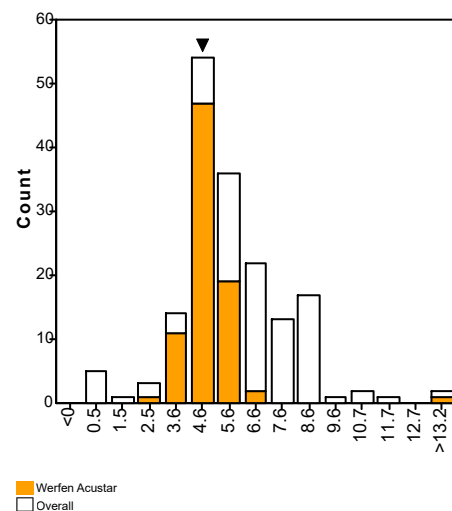
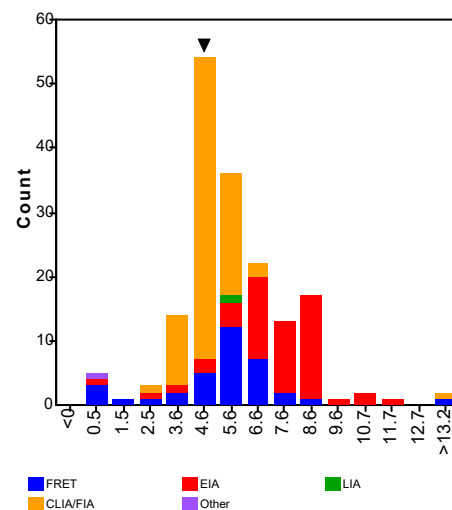
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	171	5.7	0.17	31.8	0.0 - 14.7	5.0	-0.40				
CLIA/FIA	81	4.8	0.09	14.0	3.0 - 14.7	5.0	0.36				
Werfen Acustar activity	81	4.8	0.09	14.0	3.0 - 14.7	5.0	0.36				

Other Reagents

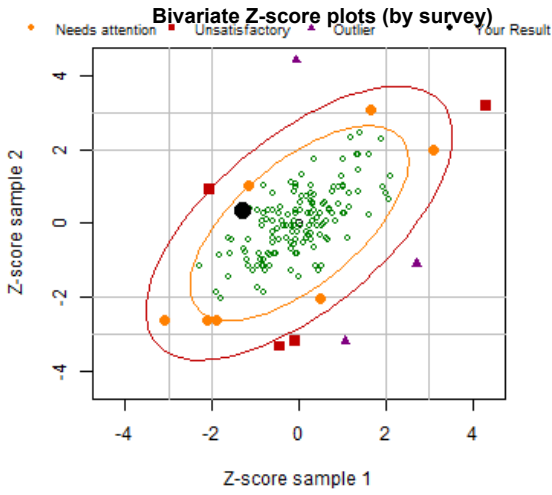
	n	assigned value	Uncert.	CV (%)	Range
Total Group	171	5.7	0.17	31.8	0.0 - 14.7
FRET	35	5.5	0.37	31.4	0.0 - 13.2
Homemade	6	5.1			0.0 - 8.0
Immucor activity	3	9.0			7.0 - 13.2
Other	3	4.0			2.5 - 5.7
Sekisui Actifluor activity	2	4.0			2.0 - 6.0
Technoclone Technofluor activity	21	5.6	0.30	19.2	0.0 - 7.8
Enzyme Immuno Assay	53	7.6	0.24	18.2	0.0 - 12.0
Other	1	7.0			-
Technoclone Technozym activity	52	7.6	0.24	18.4	0.0 - 12.0
Latex Immuno Assay	1	5.4			-
Homemade	1	5.4			-
CLIA/FIA	81	4.8	0.09	14.0	3.0 - 14.7
Other	1	0.0			-
Homemade	1	0.0			-



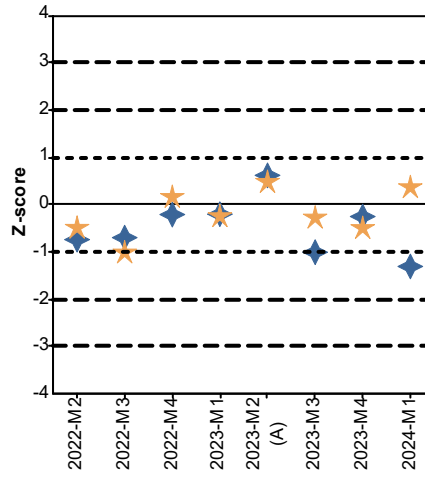
ADAMTS13 - I

ADAMTS13 Activity

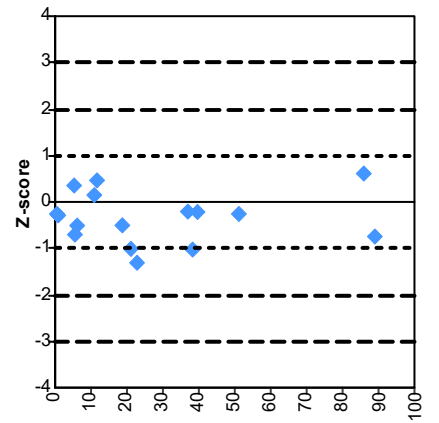
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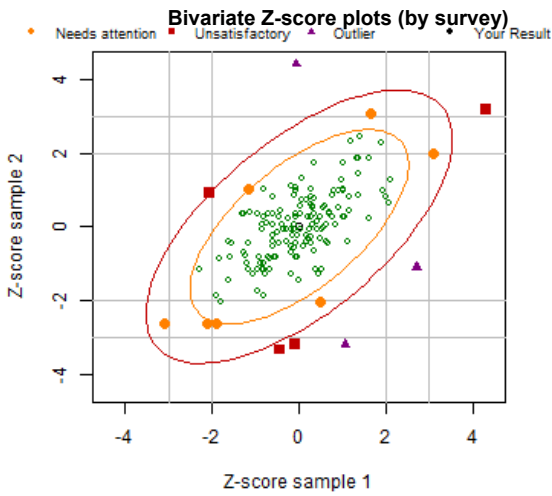
Z-score history (by survey)



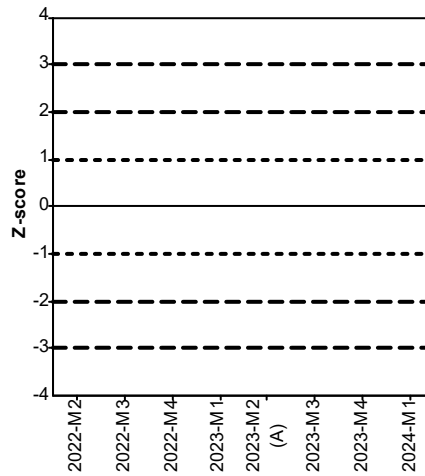
Z-score history (by consensus value)



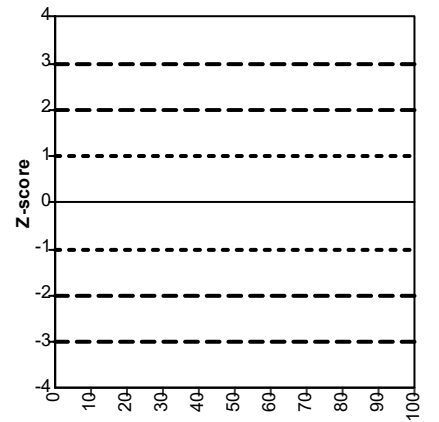
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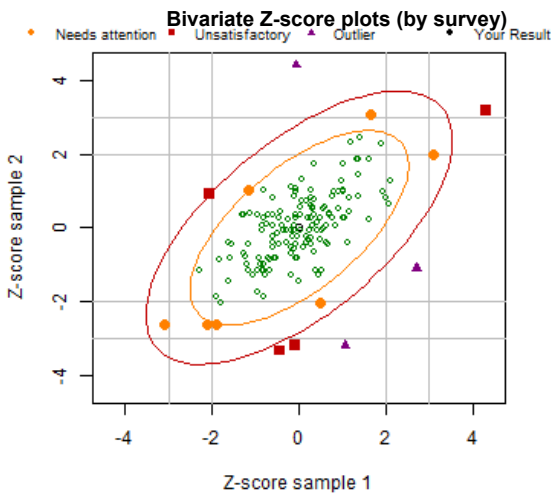
Z-score history (by survey)



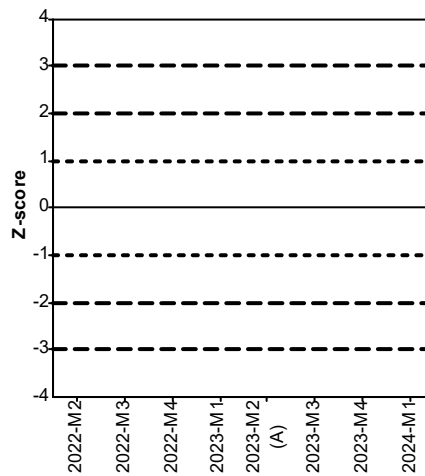
Z-score history (by consensus value)



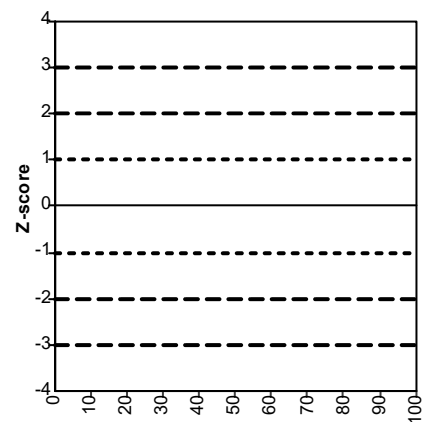
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

ADAMTS13 antigen

Sample No 24.51
Sample Details Plasma with an ADAMTS13 activity level between 20 and 30%
Prior Use None
Unit IU/mL
Expiry Date 31-oktober-2025
Homogeneity 0.8 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a $CV \leq 2.7\%$ 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.

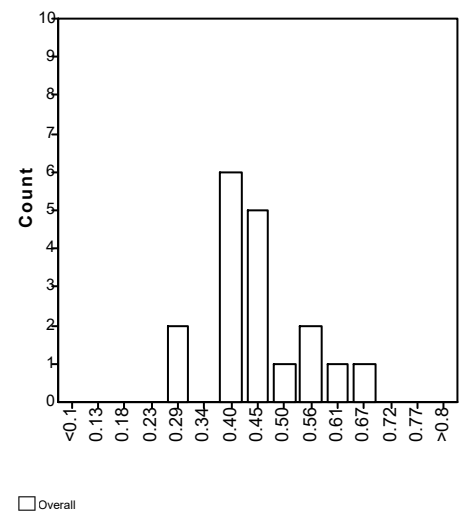
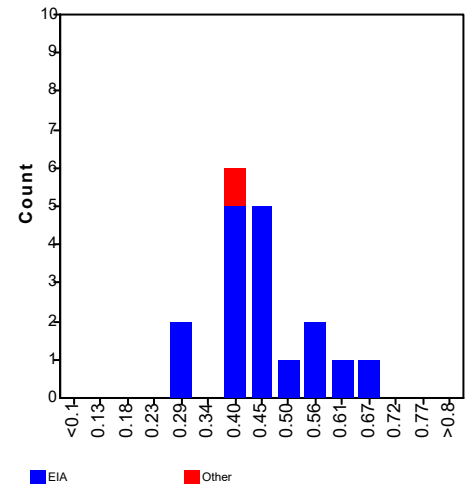
Number of Participants 179
Number of Responders 19 **Response Rate** 11 %

Comments One participant (**labcode 215**) 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 classification
Total	10	2	2	5	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	18	0.44	0.03	21.3	0.27 - 0.69
Enzyme Immuno Assay	17	0.45	0.03	22.1	0.27 - 0.69
Technozym Technozym antigen	17	0.45	0.03	22.1	0.27 - 0.69
Other	1	0.39			-
Homemade	1	0.39			-



ADAMTS13 - I **ADAMTS13 antigen**

Sample No 24.52
Sample Details Plasma with an ADAMTS13 activity level between 5 and 10%
Prior Use None
Unit IU/mL
Expiry Date 31-oktober-2025
Homogeneity 5.9 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a CV ≤ 19.7% 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.

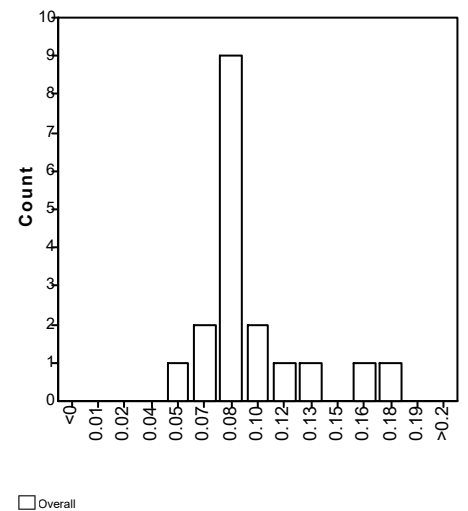
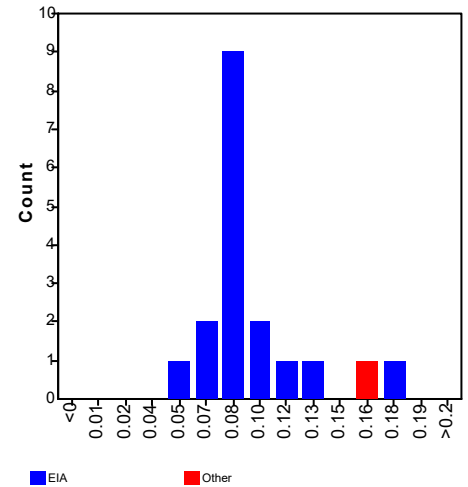
Number of Participants 179
Number of Responders 19 **Response Rate** 11 %

Comments One participant (labcode 215) 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 classification
Total	0	0	1	18	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	18	0.09	0.01	23.3	0.06 - 0.17
Enzyme Immuno Assay	17	0.09	0.01	19.7	0.06 - 0.17
Technozym Technozym antigen	17	0.09	0.01	19.7	0.06 - 0.17
Other	1	0.16			-
Homemade	1	0.16			-



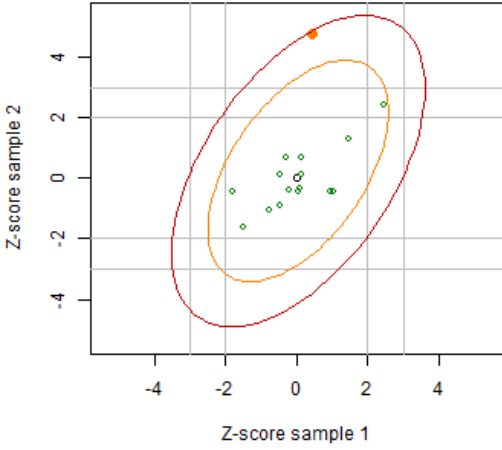
ADAMTS13 - I

ADAMTS13 antigen

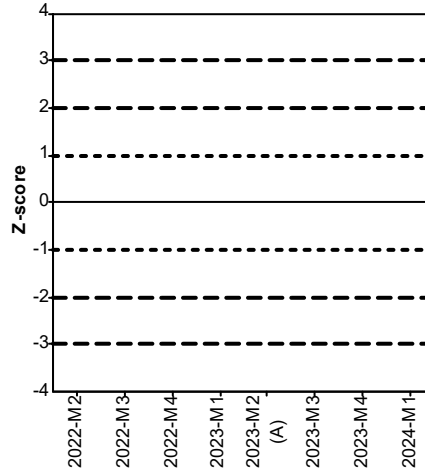
Instrument ID

Bivariate Z-score plots (by survey)

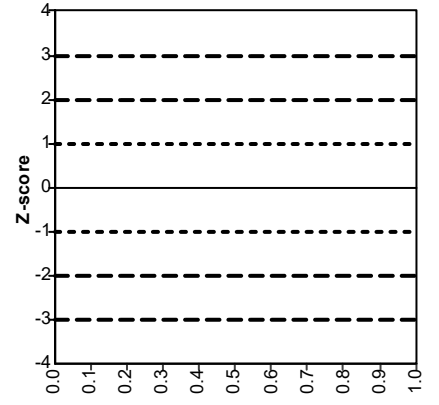
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



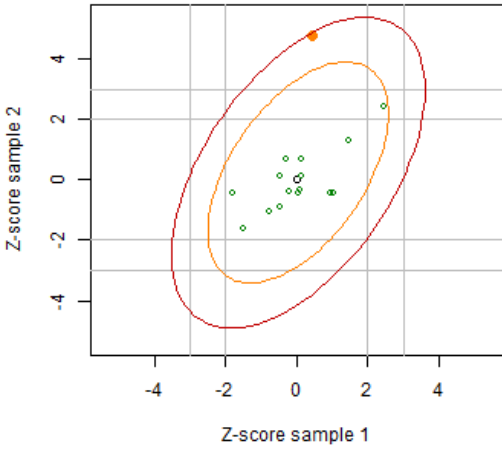
Z-score history (by consensus value)



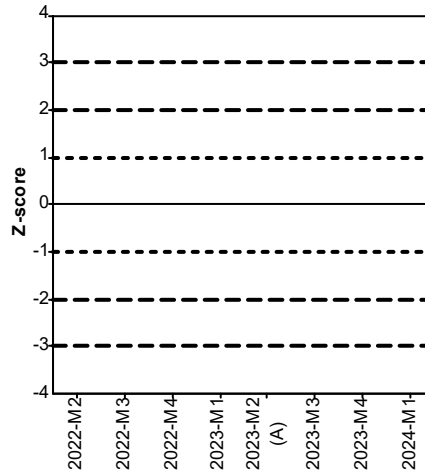
Instrument ID

Bivariate Z-score plots (by survey)

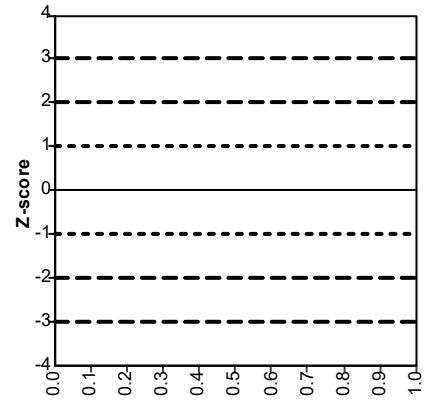
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



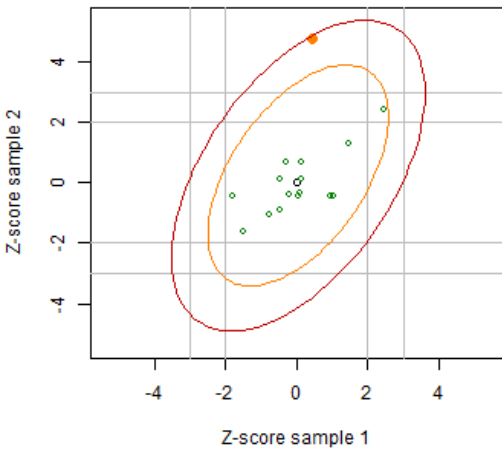
Z-score history (by consensus value)



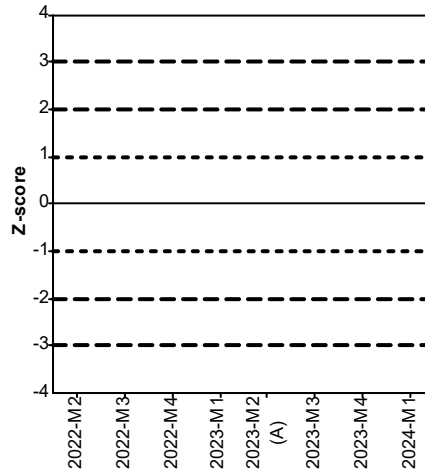
Instrument ID

Bivariate Z-score plots (by survey)

Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



Z-score history (by consensus value)

