

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-M3

Main

Labcode 1492

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Date of Issue : 05-November-2022

Survey : 2022-M3

Report : Main

Note:

In the Survey Manual 2022 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2022 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 on page 21 of the Survey Manual.

General Information

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **December 19th, 2022**.

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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Appendices are an integral part of the total report.

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: Acceptable
 ■ BV: Questionable
 ■ BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis	
ADAMTS13 - I	ADAMTS13 Activity	22.152	1	-0.81	-0.70	-0.72		
		22.153	1	-0.91	-1.02	-0.98		

ADAMTS13 - I

ADAMTS13 Activity

Sample No 22.152
Sample Details Plasma with an ADAMTS13 activity level between 5 and 10%
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2023
Homogeneity 5.8 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 19.3%** 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 149
Number of Responders 138 **Response Rate** 93 %
Comments One participant (labcode **9907191**) 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	1	0	1	149	2

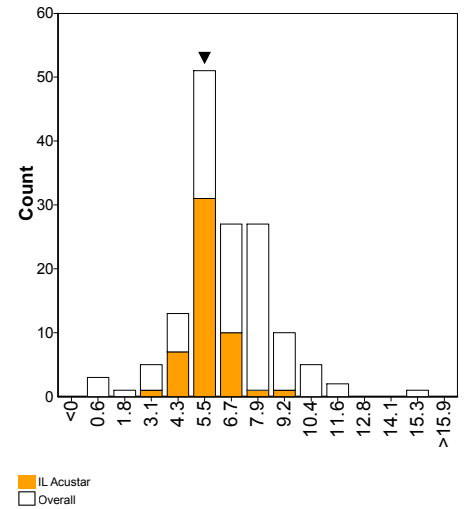
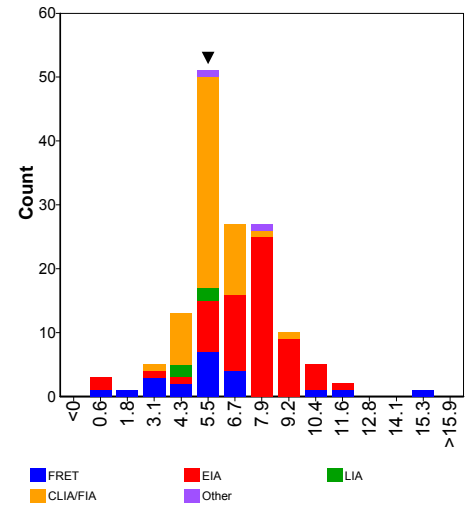
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	145	6.5	0.19	27.8	0.0 - 14.8	5.0	-0.81				
CLIA/FIA	55	5.6	0.15	15.8	2.9 - 8.7	5.0	-0.70				
IL Acustar ADAMTS13 activity	51	5.6	0.15	15.2	2.9 - 8.7	5.0	-0.72				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	145	6.5	0.19	27.8	0.0 - 14.8
FRET	21	5.6	0.70	45.7	1.0 - 14.8
Homemade	8	5.1			2.0 - 11.0
Immucor ADAMTS13 activity	1	4.5			-
Other	11	5.7	0.82	38.0	1.0 - 14.8
Sekisui Actifluor ADAMTS13 activity	1	12			-
Enzyme Immuno Assay	63	7.6	0.22	18.4	0.0 - 11.6
Homemade	3	5.0			4.5 - 11.6
Other	1	6.1			-
Technoclone ADAMTS13 activity	58	7.7	0.19	14.8	0.0 - 10.4
Technoclone ADAMTS13 activity/antigen	1	3.0			-
Latex Immuno Assay	4	4.9			4.0 - 6.0
Homemade	3	4.1			4.0 - 6.0
Other	1	5.8			-
CLIA/FIA	55	5.6	0.15	15.8	2.9 - 8.7
Technoclone Technofluor ADAMTS13 activ	4	5.8			4.3 - 7.0
Other	2	7.0			6.0 - 8.0
Homemade	1	6.0			-
Other	1	8.0			-



ADAMTS13 - I

ADAMTS13 Activity

Sample No 22.153
Sample Details Abnormal Coagulation Control Plasma
Prior Use None
Unit % or IU/dL
Expiry Date 31-January-2024
Homogeneity 2.4 % **Homogeneity Parameter** APTT
 For any method used for the measurement of this parameter with a **CV ≤ 8.0%** 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 149
Number of Responders 138 **Response Rate** 93 %
Comments One participant (labcode **9907191**) 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	20	11	34	85	3

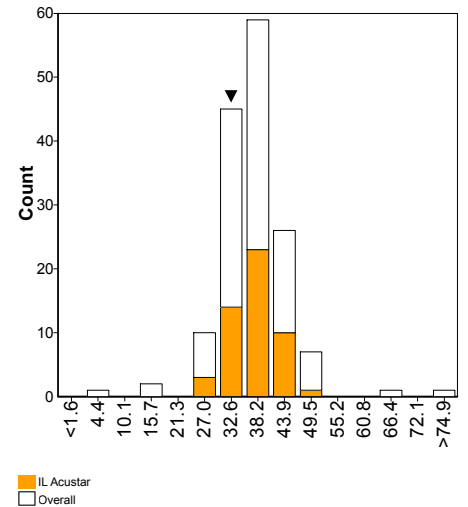
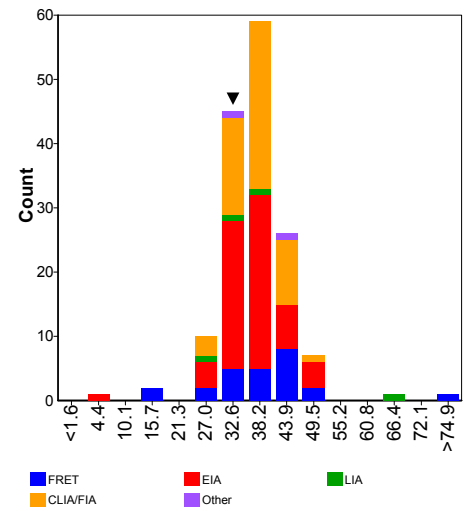
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	152	37	0.57	15.2	6 - 94	32.1	-0.91				
CLIA/FIA	55	37	0.84	13.4	26 - 52	32.1	-1.02				
IL Acustar ADAMTS13 activity	51	37	0.90	13.8	26 - 52	32.1	-0.98				

Other Reagents

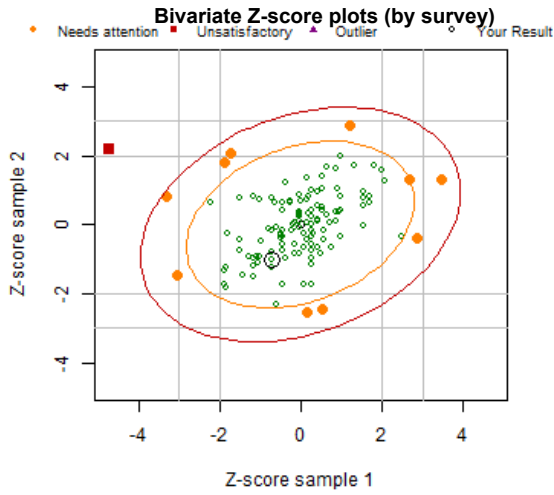
	n	assigned value	Uncert.	CV (%)	Range
Total Group	152	37	0.57	15.2	6 - 94
FRET	25	38	2.29	23.9	15 - 94
Homemade	10	38	4.17	27.6	25 - 51
Immucor ADAMTS13 activity	3	34			32 - 42
Other	11	40	3.34	22.3	15 - 94
Sekisui Actifluor ADAMTS13 activity	1	35			-
Enzyme Immuno Assay	66	37	0.78	13.8	6 - 48
Homemade	3	35			28 - 40
Other	1	32			-
Technoclone ADAMTS13 activity	61	37	0.81	13.7	6 - 48
Technoclone ADAMTS13 activity/antigen	1	41			-
Latex Immuno Assay	4	36			27 - 65
Homemade	3	34			27 - 65
Other	1	39			-
CLIA/FIA	55	37	0.84	13.4	26 - 52
Technoclone Technofluor ADAMTS13 activ	4	39			33 - 41
Other	2	38			31 - 44
Homemade	1	31			-
Other	1	44			-



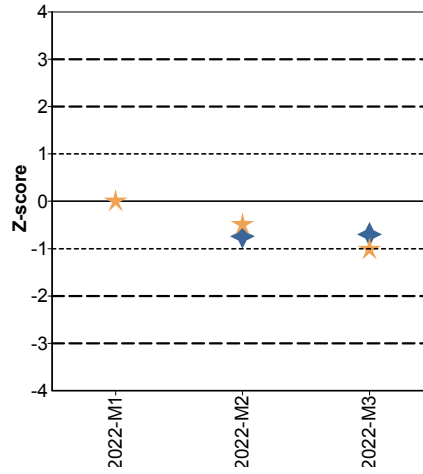
ADAMTS13 - I

ADAMTS13 Activity

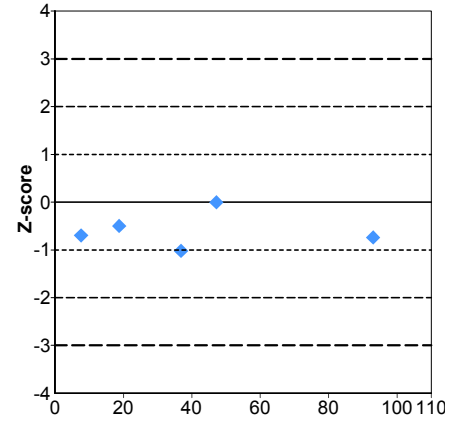
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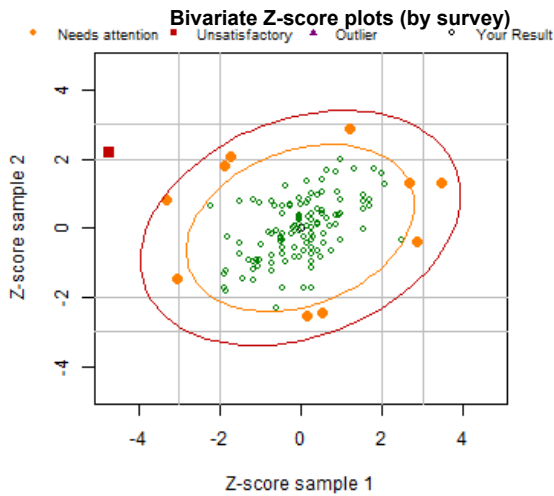
Z-score history (by survey)



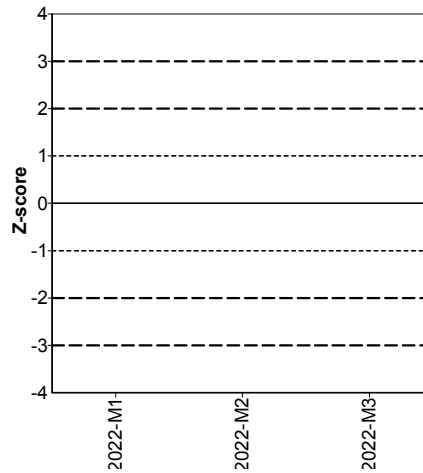
Z-score history (by consensus value)



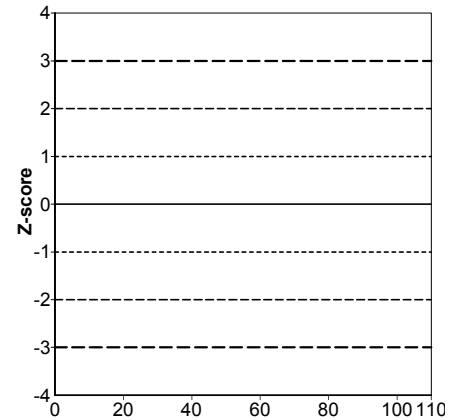
Instrument ID



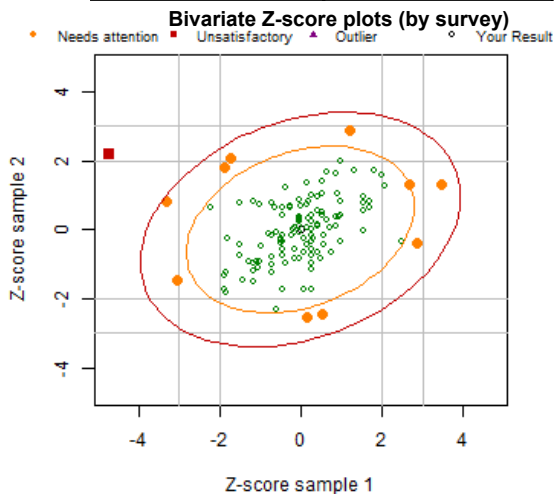
Z-score history (by survey)



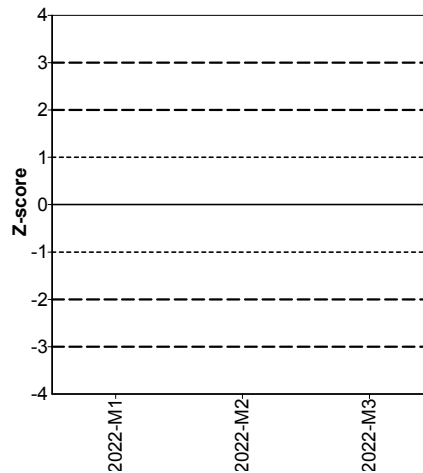
Z-score history (by consensus value)



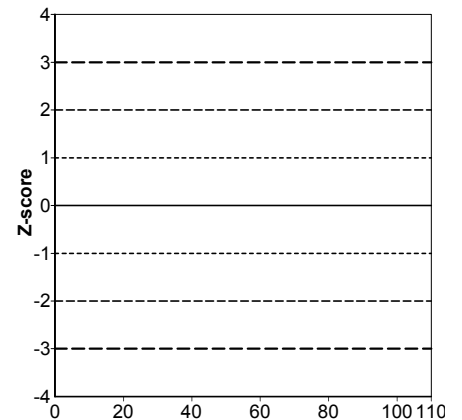
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

ADAMTS13 antigen

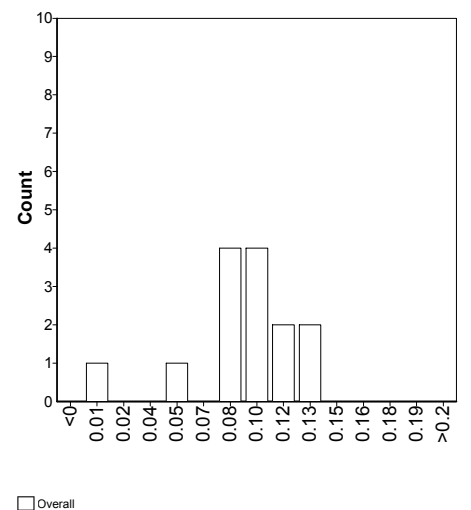
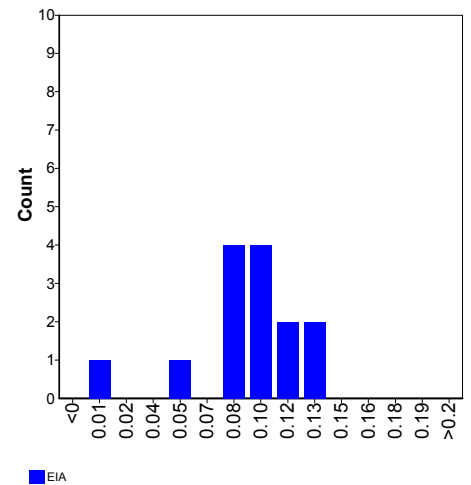
Sample No 22.152
Sample Details Plasma with an ADAMTS13 activity level between 5 and 10%
Prior Use None
Unit IU/mL
Expiry Date 31-December-2023
Homogeneity 5.8 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 19.3%** the criterion for homogeneity 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 149
Number of Responders 15 **Response Rate** 10 %
Comments Two participants (labcodes **215** and **9055**) selected the wrong unit when submitting the result. These results were excluded in the statistical evaluation.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	2	0	0	14	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	14	0.10	0.01	24.9	0.00 - 0.14
Technozym ADAMTS13 activity/antigen	4	0.10			0.00 - 0.11
Technozym ADAMTS13 antigen	10	0.10	0.01	24.7	0.05 - 0.14



ADAMTS13 - I

ADAMTS13 antigen

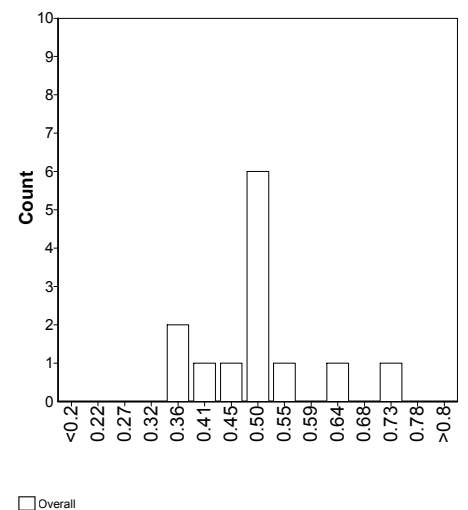
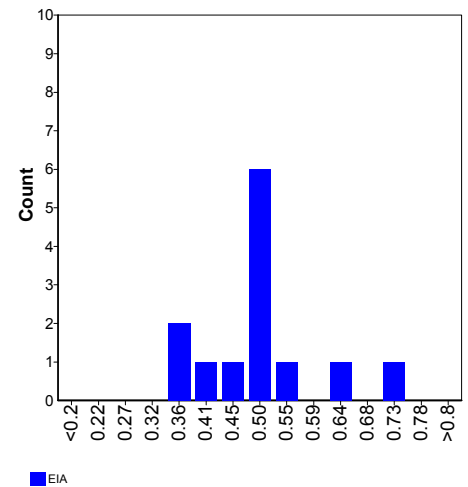
Sample No 22.153
Sample Details Abnormal Coagulation Control Plasma
Prior Use None
Unit IU/mL
Expiry Date 31-January-2024
Homogeneity 2.4 % **Homogeneity Parameter** APTT
 For any method used for the measurement of this parameter with a **CV ≤ 8.0%** the criterion for homogeneity could not be met and 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 149
Number of Responders 15 **Response Rate** 10 %
Comments Two participants (labcodes **215** and **9055**) selected the wrong unit when submitting the result. These results were excluded in the statistical evaluation.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	8	2	5	0	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	13	0.49	0.03	17.1	0.36 - 0.74
Technozym ADAMTS13 activity/antigen	3	0.47			0.43 - 0.49
Technozym ADAMTS13 antigen	10	0.50	0.04	20.6	0.36 - 0.74



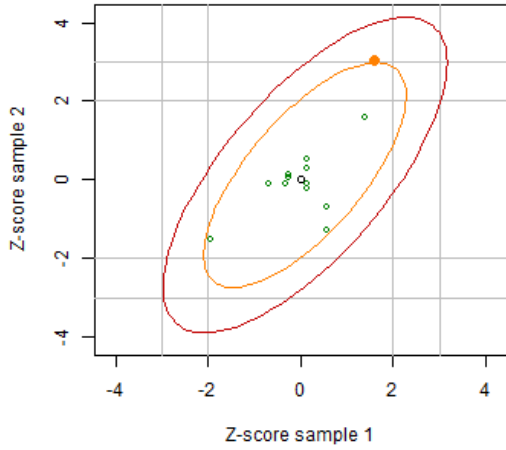
ADAMTS13 - I

ADAMTS13 antigen

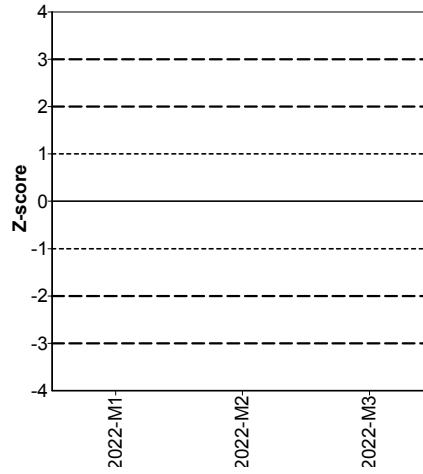
Instrument ID

Bivariate Z-score plots (by survey)

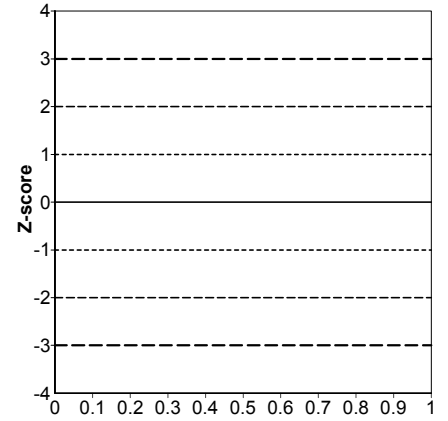
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



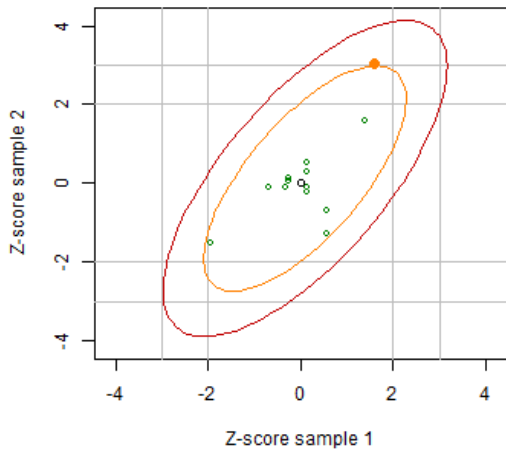
Z-score history (by consensus value)



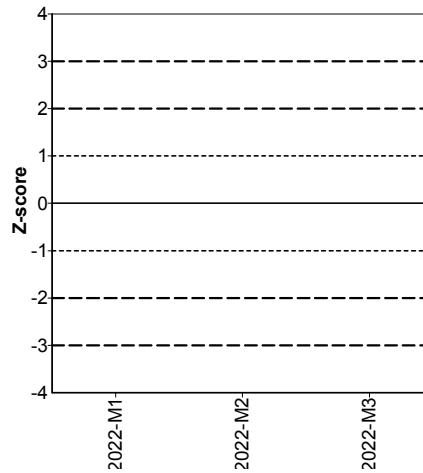
Instrument ID

Bivariate Z-score plots (by survey)

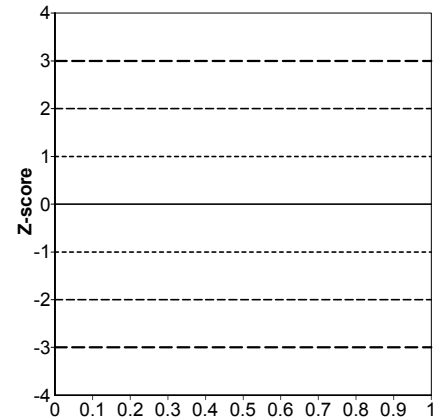
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



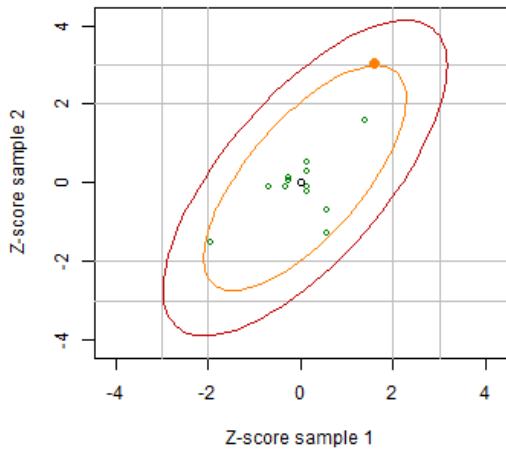
Z-score history (by consensus value)



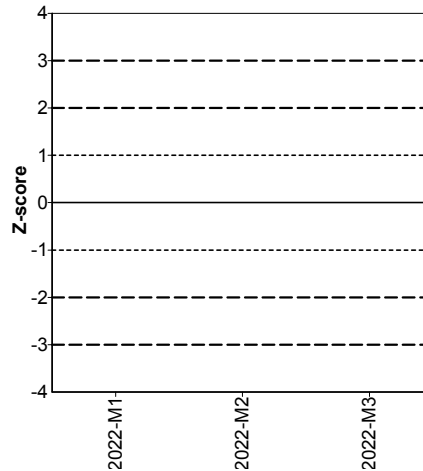
Instrument ID

Bivariate Z-score plots (by survey)

Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



Z-score history (by consensus value)

