

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-M4

Main

Labcode 1492

Date of Issue : 31-January-2023

Survey : 2022-M4

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.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **March 14th, 2023**.

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.

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 ($-2 \leq Z\text{-score} \leq 2$)
 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 Activty	22.193	1	-0.04	-0.21	-0.19	
		22.194	1	-0.32	0.15	0.14	

ADAMTS13 - I	ADAMTS13 Activity
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Sample No 22.193
Sample Details Abnormal Coagulation Control Plasma
Prior Use 2022-M3
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 140 **Response Rate** 94 %

Comments One participant (labcode **9907191**) 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 22.193 are good comparable with those of sample 22.153 in survey 2022-M3.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	22	8	36	84	3

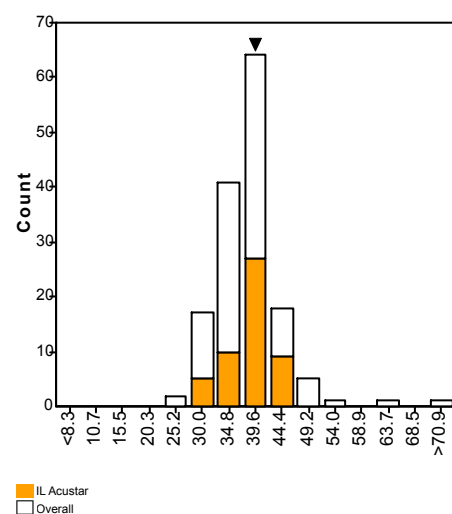
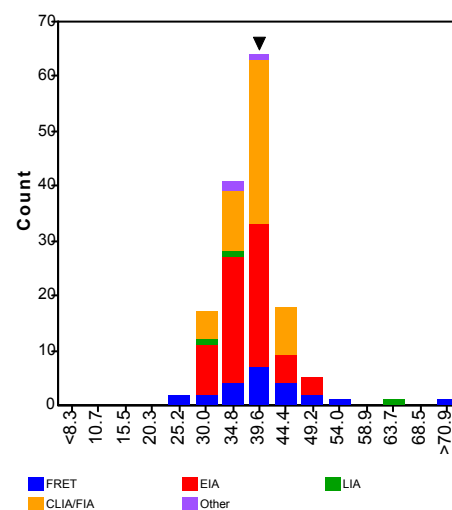
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	150	38	0.49	12.7	25 - 72	37.9	-0.04				
CLIA/FIA	55	39	0.65	10.0	28 - 46	37.9	-0.21				
IL Acustar ADAMTS13 activity	51	39	0.72	10.6	28 - 46	37.9	-0.19				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	150	38	0.49	12.7	25 - 72
FRET	23	40	2.04	19.7	25 - 72
Homemade	10	38	4.79	31.6	25 - 72
Immucor ADAMTS13 activity	3	47			44 - 49
Other	9	39			36 - 44
Sekisui Actifluor ADAMTS13 activity	1	32			-
Enzyme Immuno Assay	66	37	0.71	12.4	29 - 51
Homemade	3	33			31 - 34
Other	1	46			-
Technoclone ADAMTS13 activity	61	37	0.71	11.9	29 - 51
Technoclone ADAMTS13 activity/antigen	1	39			-
Latex Immuno Assay	3	35			31 - 63
Homemade	2	47			31 - 63
Other	1	35			-
CLIA/FIA	55	39	0.65	10.0	28 - 46
Technoclone Technofluor ADAMTS13 ac	4	39			35 - 42
Other	3	36			36 - 40
Homemade	2	38			36 - 40
Other	1	36			-



ADAMTS13 - I	ADAMTS13 Activity
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Sample No 22.194
Sample Details Plasma with an ADAMTS13 activity level between 10 and 20%
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2023
Homogeneity 3.6 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a CV ≤ 12.0% 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 140 **Response Rate** 94 %

Comments One participant (labcode **9907191**) selected the wrong unit when submitting the result. This result was excluded in the statistical evaluation.

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

235 : 1.6%

1086 : 0%

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	1	5	145	2

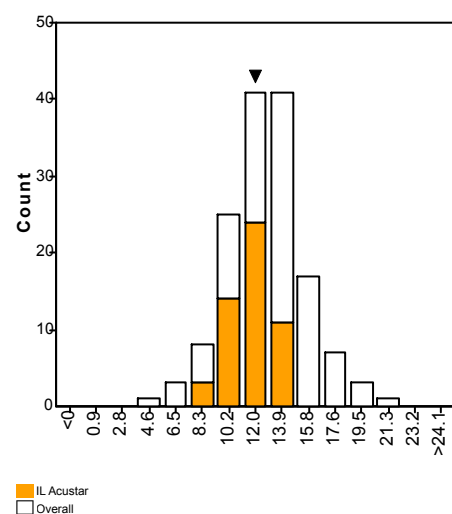
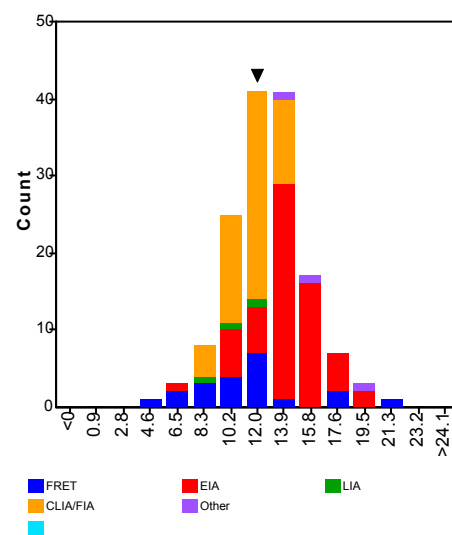
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	147	13	0.24	18.4	4 - 22	11.9	-0.32				
CLIA/FIA	56	12	0.24	12.1	8 - 14	11.9	0.15				
IL Acustar ADAMTS13 activity	52	12	0.25	12.1	8 - 14	11.9	0.14				

Other Reagents

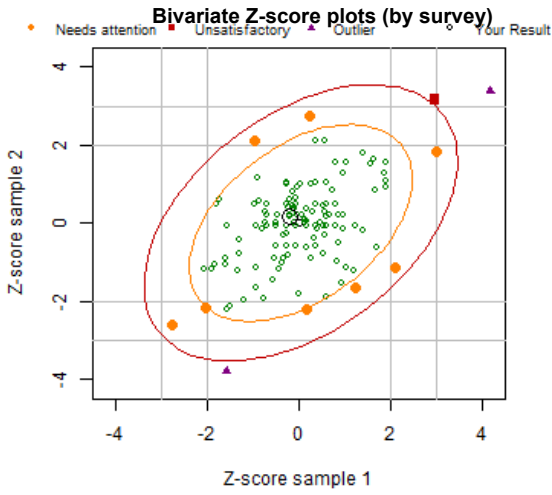
	n	assigned value	Uncert.	CV (%)	Range
Total Group	147	13	0.24	18.4	4 - 22
FRET	21	11	0.90	29.9	4 - 22
Homemade	8	11			4 - 22
Immucor ADAMTS13 activity	3	7.0			6.0 - 18.0
Other	9	12			9 - 13
Sekisui Actifluor ADAMTS13 activity	1	18			-
Enzyme Immuno Assay	64	14	0.29	13.2	7 - 20
Homemade	2	11			11 - 11
Other	1	16			-
Technoclone ADAMTS13 activity	61	14	0.27	12.0	7 - 20
Latex Immuno Assay	3	10			9 - 12
Homemade	2	9.5			9.0 - 10.0
Other	1	12			-
CLIA/FIA	56	12	0.24	12.1	8 - 14
Technoclone Technofluor ADAMTS13 ac	4	12			9 - 13
Other	3	15			14 - 19
Homemade	2	17			14 - 19
Other	1	15			-



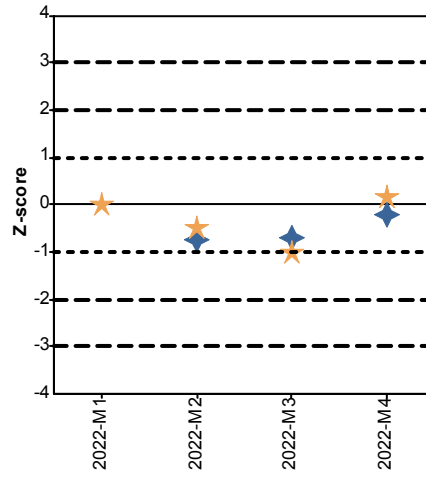
ADAMTS13 - I

ADAMTS13 Activity

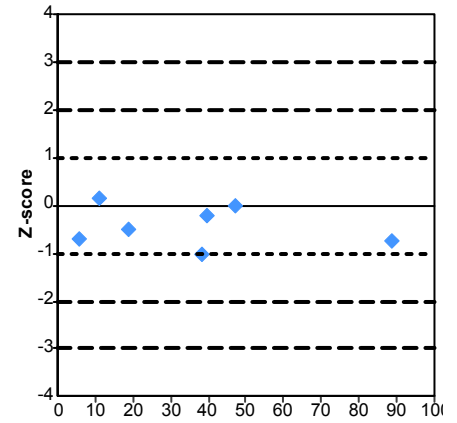
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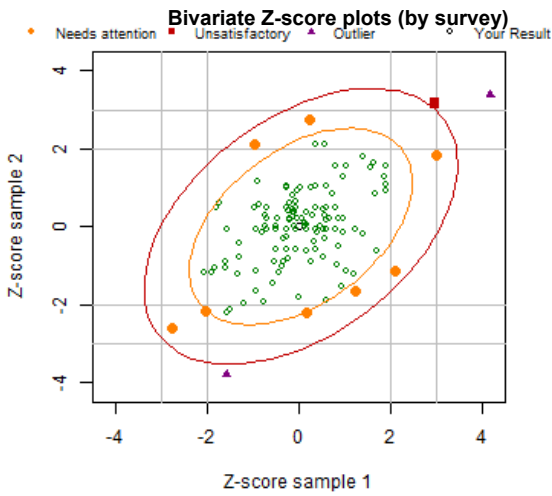
Z-score history (by survey)



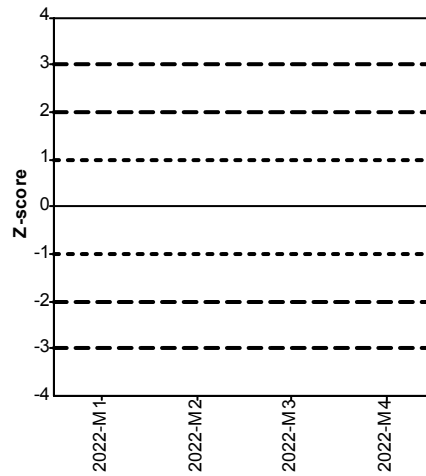
Z-score history (by consensus value)



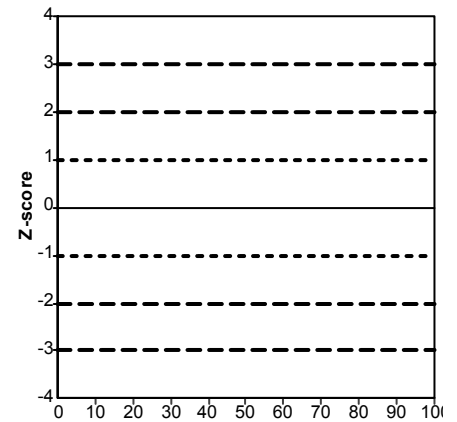
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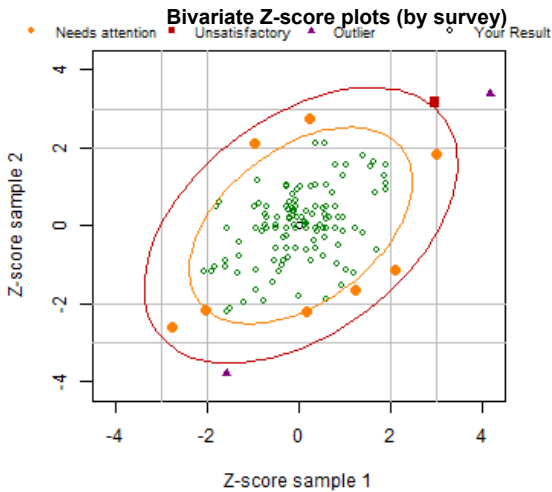
Z-score history (by survey)



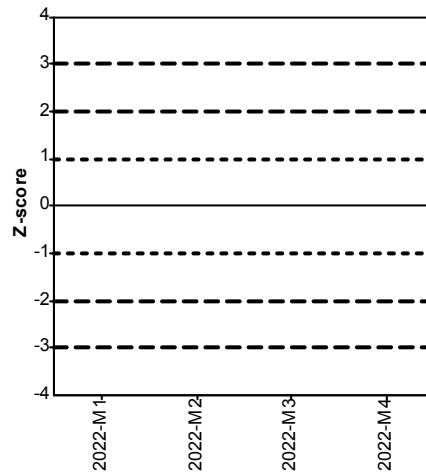
Z-score history (by consensus value)



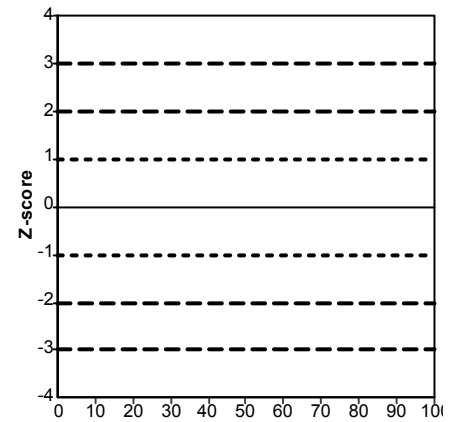
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I	ADAMTS13 antigen
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Sample No 22.193
Sample Details Abnormal Coagulation Control Plasma
Prior Use 2022-M3
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 17

Response Rate 11 %

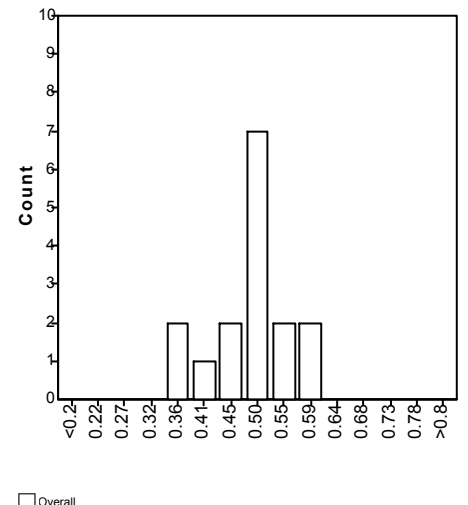
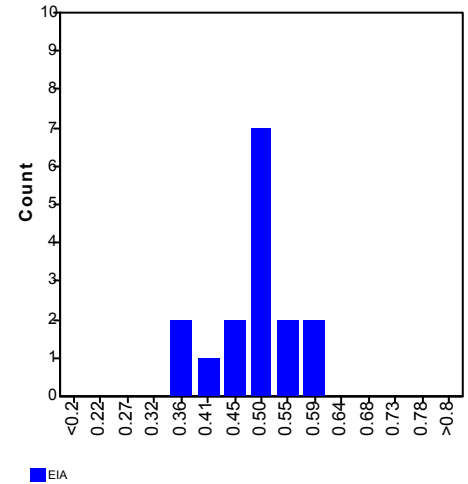
Comments The following participant reported a deviating result which was excluded in the statistical evaluation: **1167** : 0.29%

For the most frequently used reagents (n ≥ 10) the results of sample 22.193 are good comparable with those of sample 22.153 in survey 2022-M3.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	10	2	3	2	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	16	0.49	0.02	15.5	0.36 - 0.60
Technozym ADAMTS13 activity/antigen	4	0.46			0.36 - 0.49
Technozym ADAMTS13 antigen	12	0.50	0.03	14.5	0.36 - 0.60



ADAMTS13 - I **ADAMTS13 antigen**

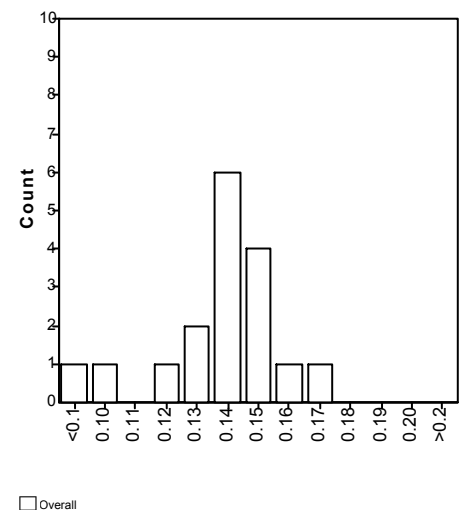
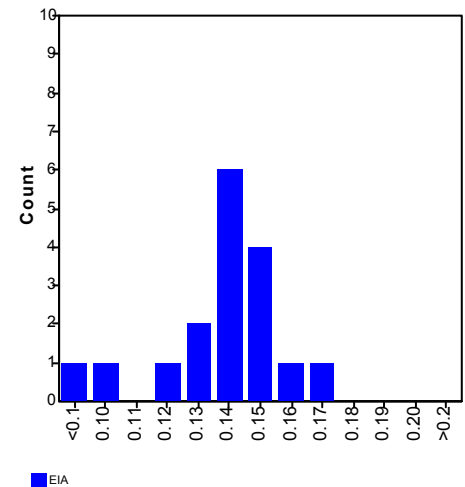
Sample No 22.194
Sample Details Plasma with an ADAMTS13 activity level between 10 and 20%
Prior Use None
Unit IU/mL
Expiry Date 31-December-2023
Homogeneity 3.6 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 12.0%** the criterion for homogeneity 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 17 **Response Rate** 11 %
Comments None.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	0	0	17	0

Other Reagents

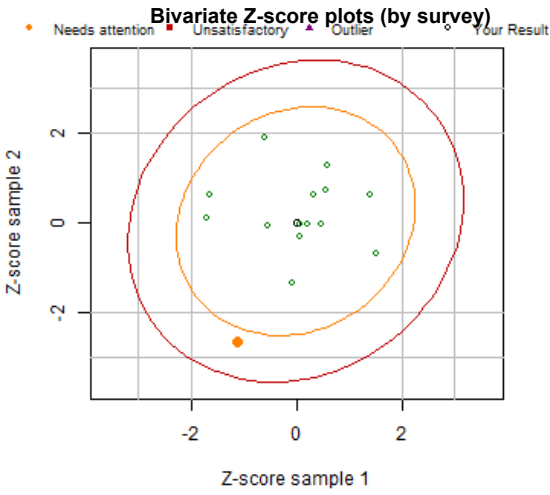
	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	17	0.14	0.00	10.9	0.05 - 0.17
Technozym ADAMTS13 activity/antigen	4	0.14			0.12 - 0.17
Technozym ADAMTS13 antigen	13	0.14	0.00	9.4	0.05 - 0.16



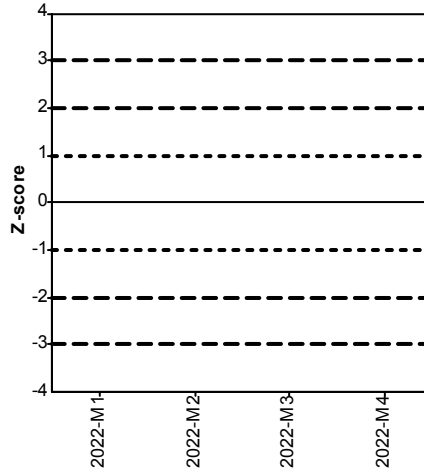
ADAMTS13 - I

ADAMTS13 antigen

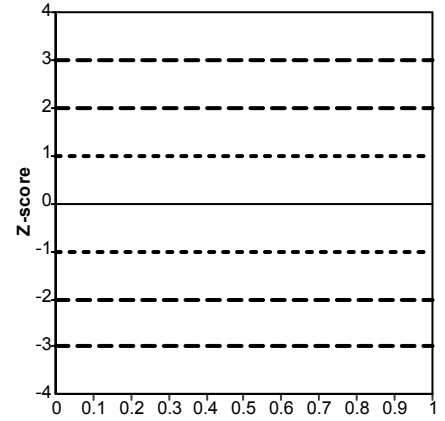
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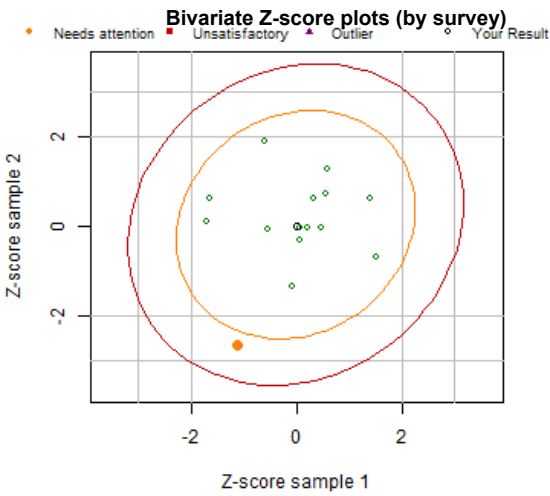
Z-score history (by survey)



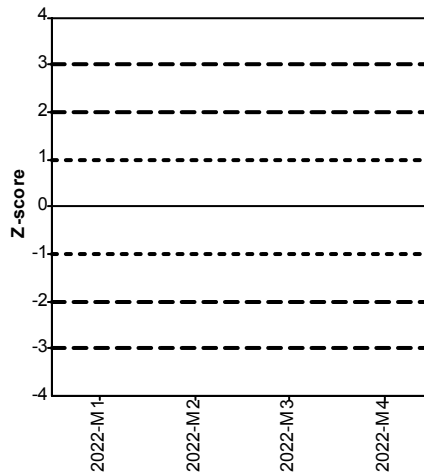
Z-score history (by consensus value)



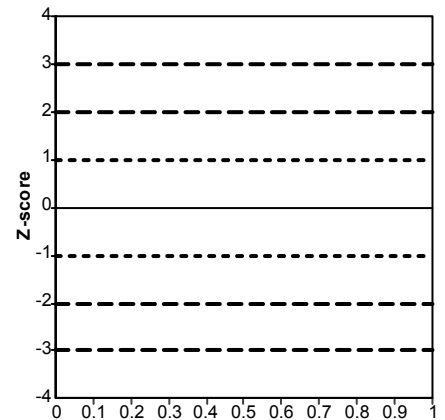
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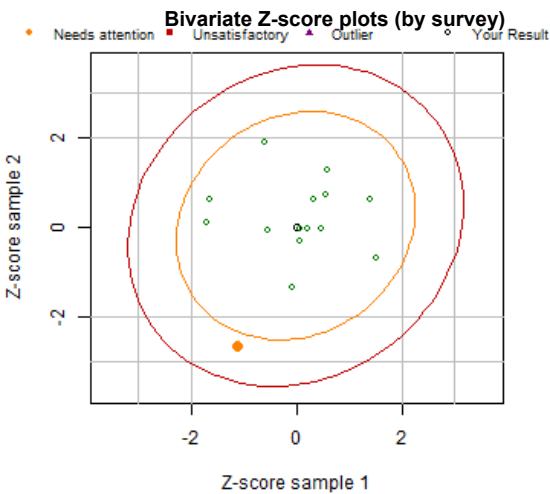
Z-score history (by survey)



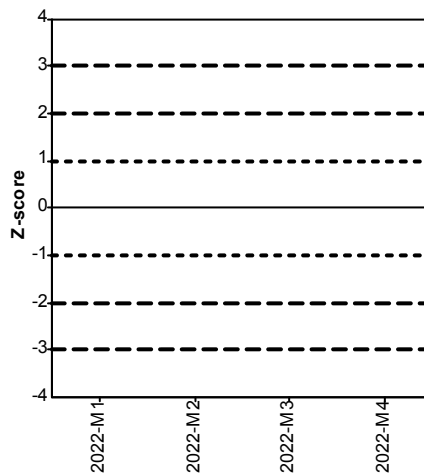
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

