

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-M2

Main

Labcode 1492

Date of Issue : 26-juli-2024

Survey : 2024-M2

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 **September 19th, 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 Activty	24.101	1	-0.93	-0.57	-0.57	
		24.102	1	-0.51	-0.21	-0.21	

ADAMTS13 - I	ADAMTS13 Activity
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Sample No 24.101
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 $CV \leq 3.3\%$ 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 184
Number of Responders 171 **Response Rate** 93 %

Comments All participants who used the equipment Technoclone Ceveron for their ADAMTS 13 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.

The following participant (labcode: **1196 instr. 1 and 2**) reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the samples 24.101 and 24.102.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	113	16	20	40	3

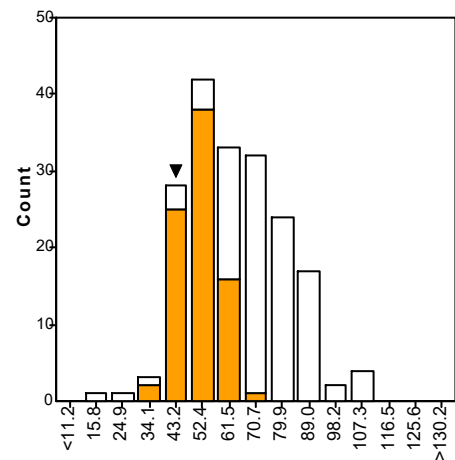
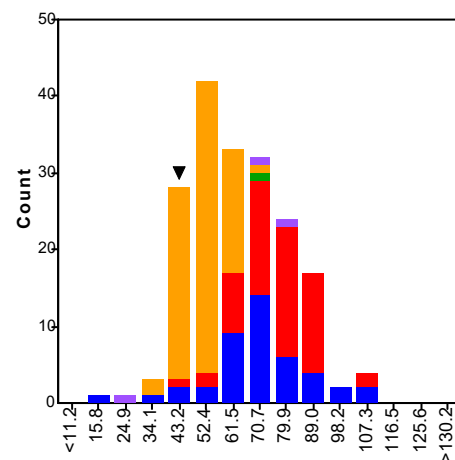
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result		your result		your result	
						your result	z-score	your result	z-score	your result	z-score
Total Group	187	63	1.53	26.6	17 - 111	47.5	-0.93				
CLIA/FIA	82	51	0.86	12.2	36 - 67	47.5	-0.57				
Werfen Acustar activity	82	51	0.86	12.2	36 - 67	47.5	-0.57				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	187	63	1.53	26.6	17 - 111
FRET	43	71	2.83	21.0	17 - 111
Homemade	13	77	6.03	22.6	43 - 99
Immucor activity	4	77			17 - 111
Other	3	70			34 - 103
Sekisui Actifluor activity	2	59			57 - 60
Technoclone Technofluor activity	21	69	1.50	8.0	48 - 78
Enzyme Immuno Assay	58	76	1.90	15.1	39 - 105
Homemade	1	59			-
Technoclone Technozym activity	56	77	1.88	14.7	39 - 105
Technoclone Technozym activity/antigen	1	85			-
Latex Immuno Assay	1	67			-
Homemade	1	67			-
CLIA/FIA	82	51	0.86	12.2	36 - 67
Other	3	69			23 - 77
Homemade	2	50			23 - 77
Other	1	69			-



ADAMTS13 - I	ADAMTS13 Activity
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Sample No	24.102		
Sample Details	Plasma with an ADAMTS13 activity level <2.5%		
Prior Use	None		
Unit	% or IU/dL		
Expiry Date	31-januari-2026		
Homogeneity	0.0 %	Homogeneity Parameter	ADAMTS13
Number of Participants	184	Response Rate	93 %
Number of Responders	171		
Comments	All participants who used the equipment Technoclone Ceveron for their ADAMTS 13 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.		

The following participant (labcode: **1196 instr. 1 and 2**) reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the samples 24.101 and 24.102.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	2	0	0	188	2

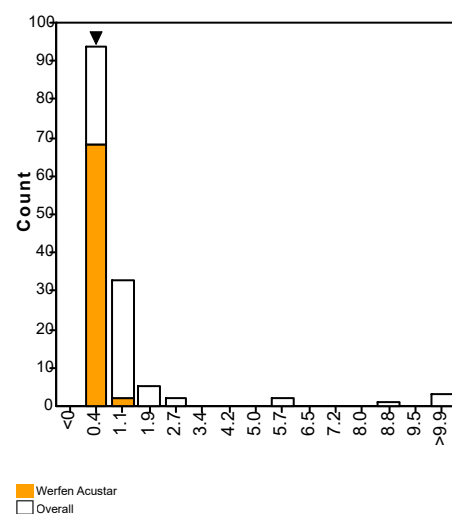
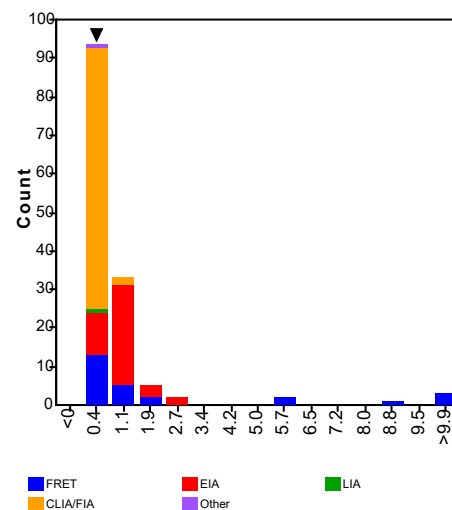
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Total Group	140	0.5	0.05	87.3	0.0 - 28.8	0.3	-0.51				
CLIA/FIA	70	0.3	0.02	37.0	0.0 - 1.0	0.3	-0.21				
Werfen Acustar activity	70	0.3	0.02	37.0	0.0 - 1.0	0.3	-0.21				

Other Reagents

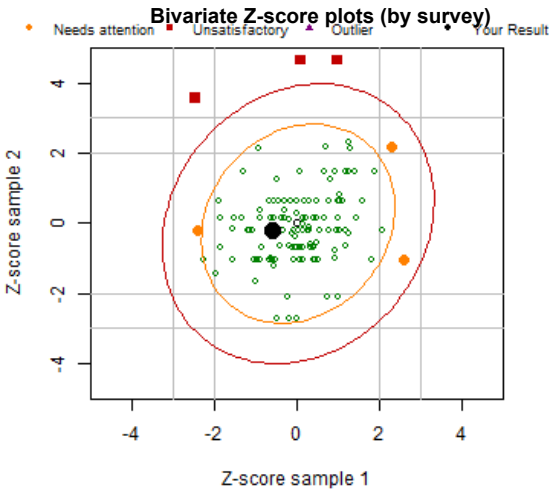
	n	assigned value	Uncert.	CV (%)	Range
Total Group	140	0.5	0.05	87.3	0.0 - 28.8
FRET	26	1.4	0.52	147.8	0.0 - 28.8
Homemade	6	0.1			0.0 - 6.0
Immucor activity	2	26			24 - 29
Other	3	9.0			0.0 - 14.0
Sekisui Actifluor activity	1	6.0			-
Technoclone Technofluor activity	14	0.7	0.27	121.2	0.0 - 2.0
Enzyme Immuno Assay	42	0.9	0.09	47.1	0.0 - 3.0
Technoclone Technozym activity	41	1.0	0.08	43.5	0.0 - 3.0
Technoclone Technozym activity/antigen	1	0.0			-
Latex Immuno Assay	1	0.0			-
Homemade	1	0.0			-
CLIA/FIA	70	0.3	0.02	37.0	0.0 - 1.0
Other	1	0.0			-
Homemade	1	0.0			-



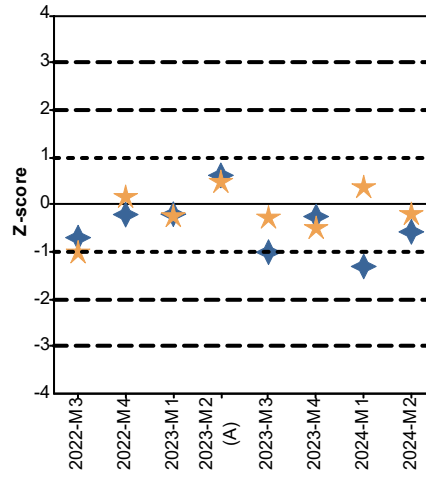
ADAMTS13 - I

ADAMTS13 Activity

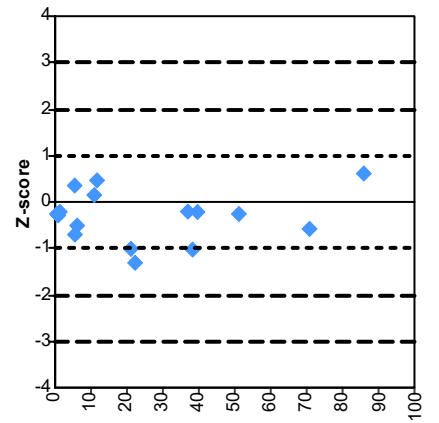
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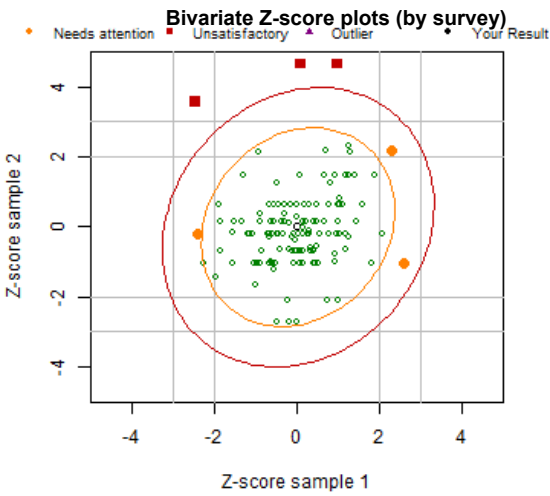
Z-score history (by survey)



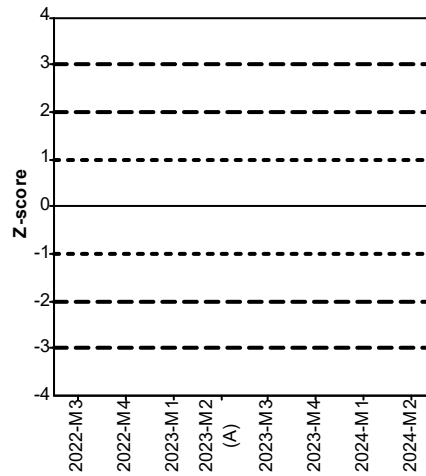
Z-score history (by consensus value)



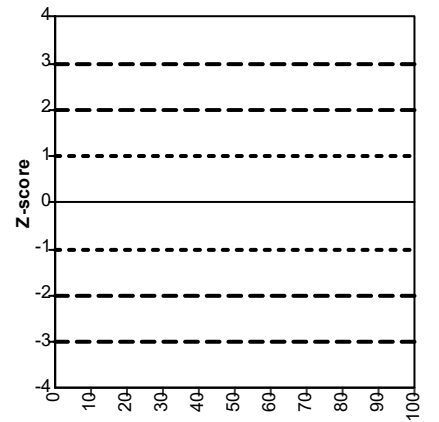
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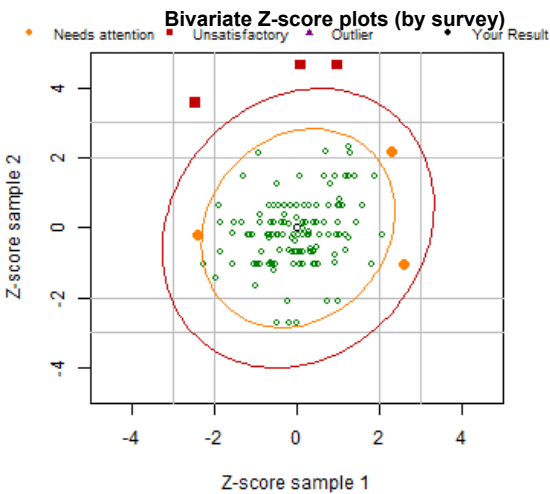
Z-score history (by survey)



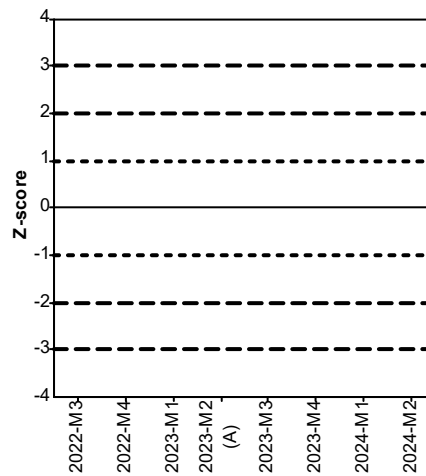
Z-score history (by consensus value)



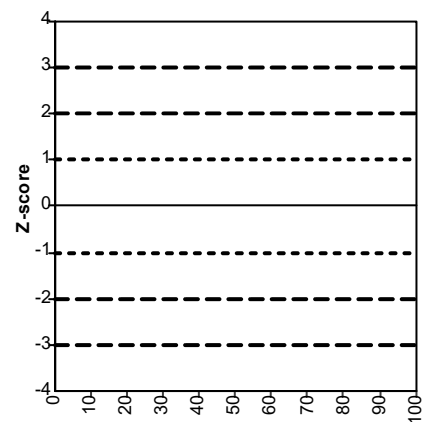
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I **ADAMTS13 antigen**

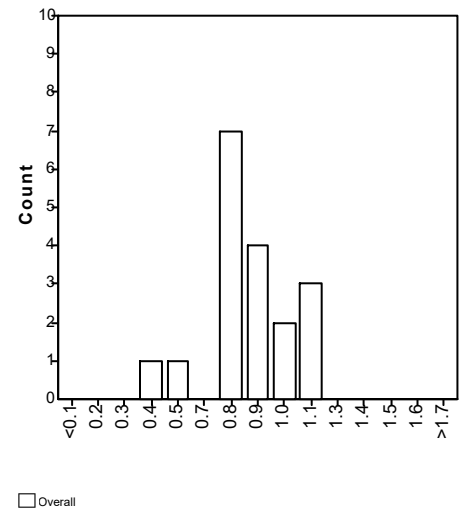
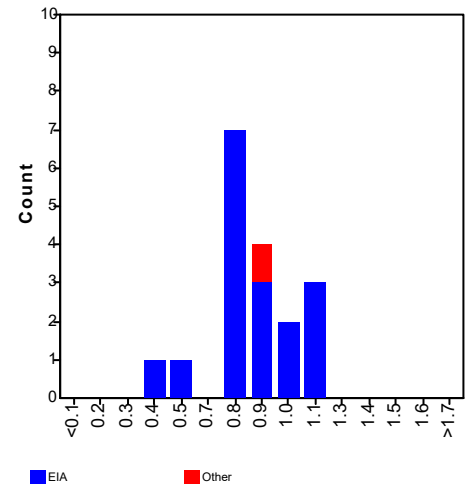
Sample No 24.101
Sample Details Abnormal Coagulation Control Plasma
Prior Use None
Unit IU/mL
Expiry Date 31-december-2025
Homogeneity 1.0 % **Homogeneity Parameter** APTT
 For any method used for the measurement of this parameter with a CV ≤ 3.3% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 184
Number of Responders 23 **Response Rate** 13 %
Comments The results of 2 participants (**labcodes 215 and 950**) were excluded because they reported results with an incorrect unit (IU/mL instead of IU/dL).

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	22	1	0	0	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	18	0.88	0.05	20.8	0.40 - 1.20
Enzyme Immuno Assay	17	0.88	0.06	22.4	0.40 - 1.20
Technozym Technozym activity/antigen	3	0.89			0.82 - 1.20
Technozym Technozym antigen	14	0.85	0.07	23.7	0.40 - 1.14
Other	1	0.90			-
Homemade	1	0.90			-



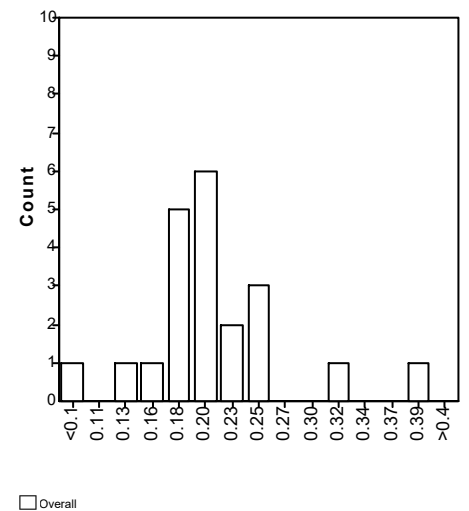
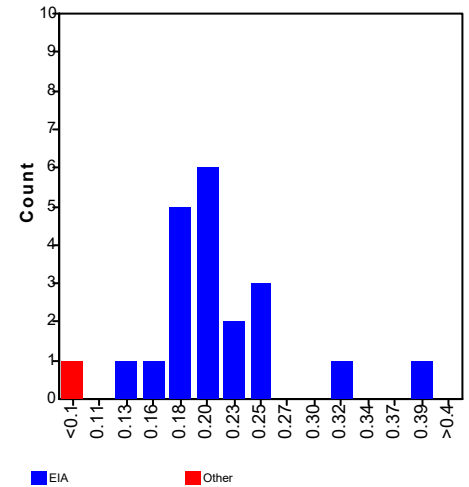
ADAMTS13 - I **ADAMTS13 antigen**

Sample No 24.102
Sample Details Plasma with an ADAMTS13 activity level <2.5%
Prior Use None
Unit IU/mL
Expiry Date 31-januari-2026
Homogeneity 0.0 % **Homogeneity Parameter** ADAMTS13
Number of Participants 184
Number of Responders 23 **Response Rate** 13 %
Comments The result of 1 participant (**labcodes 950**) was excluded because they reported a result with an incorrect unit (IU/mL instead of IU/dL).

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classification
Total	0	1	0	22	0

Other Reagents

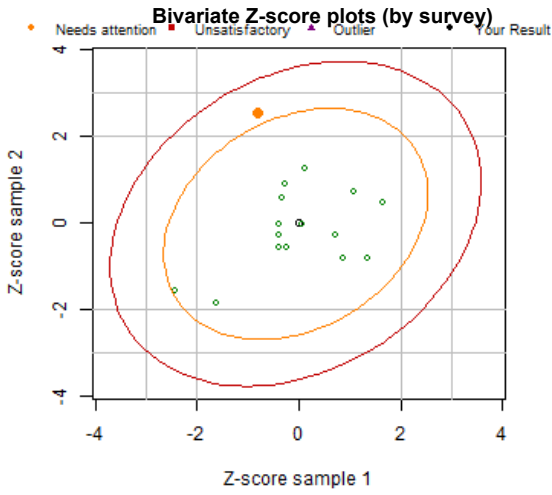
	n	assigned value	Uncert.	CV (%)	Range
Total Group	21	0.21	0.01	20.8	0.05 - 0.40
Enzyme Immuno Assay	20	0.21	0.01	18.4	0.14 - 0.40
Technozym Technozym activity/antigen	3	0.25			0.23 - 0.40
Technozym Technozym antigen	17	0.20	0.01	16.5	0.14 - 0.31
Other	1	0.05			-
Homemade	1	0.05			-



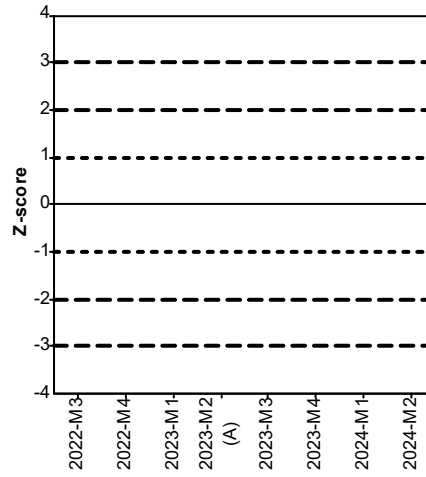
ADAMTS13 - I

ADAMTS13 antigen

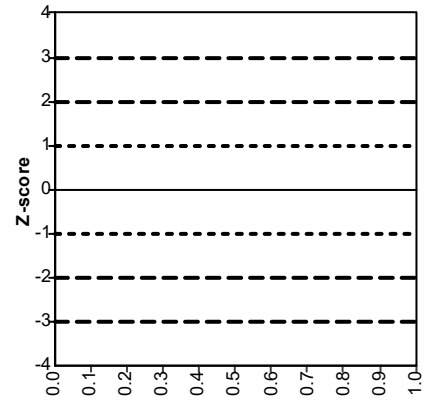
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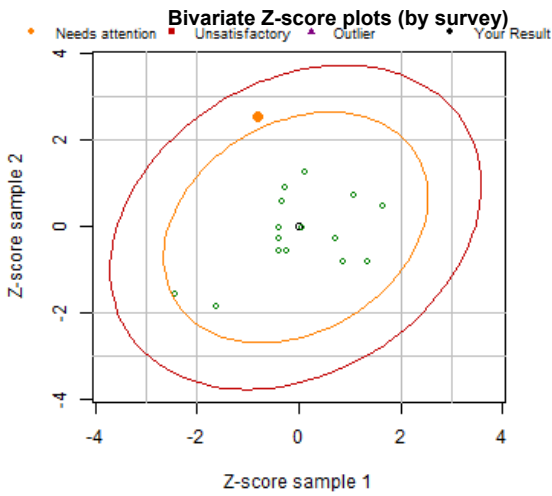
Z-score history (by survey)



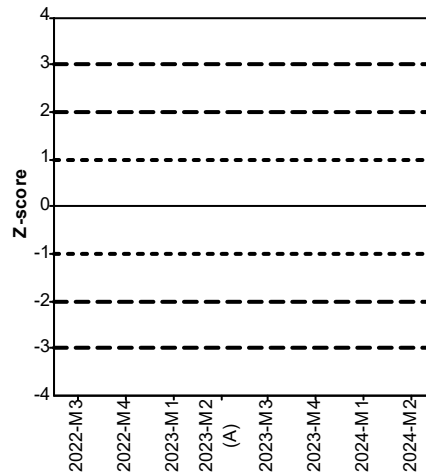
Z-score history (by consensus value)



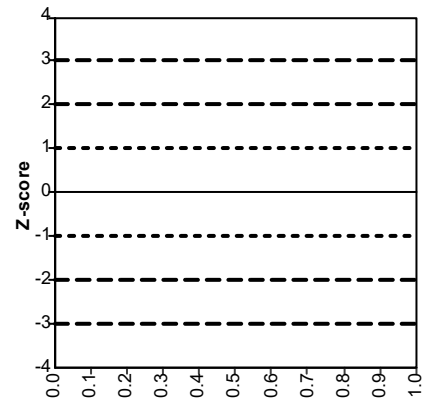
Instrument ID



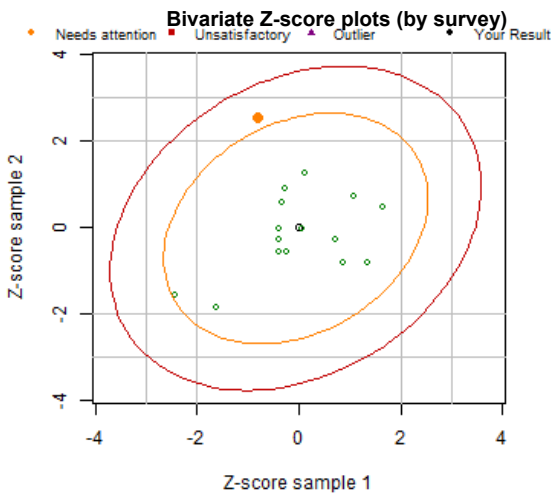
Z-score history (by survey)



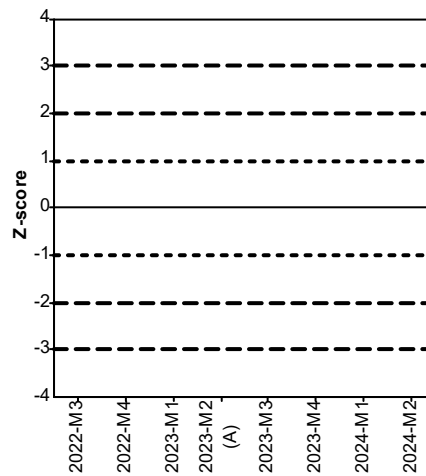
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

