ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2023-M1
Main
Labcode 1492

Copyright © 2023
ECAT Foundation

Date of Issue : 11-May-2023

Survey : 2023-M1

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 **June 20th, 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
General terms of delivery are applicable to all our services.

All rights reserved. No part of this report may be reproduced, stored in a retrieval system, or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior permission from the ECAT Foundation.

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	23.51	1	-0.22	-0.20	-0.09	
		23.52	1	0.44	-0.25	-0.43	

ADAMTS13 - I

ADAMTS13 Activity

Sample No 23.51
Sample Details Abnormal Coagulation Control Plasma
Prior Use 2022-M4 and 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 161
Number of Responders 150 **Response Rate** 93 %
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 23.51 are good comparable with those of sample 22.193 and 22.153 in survey 2022-M4 and 2022-M3.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	10	16	21	117	2

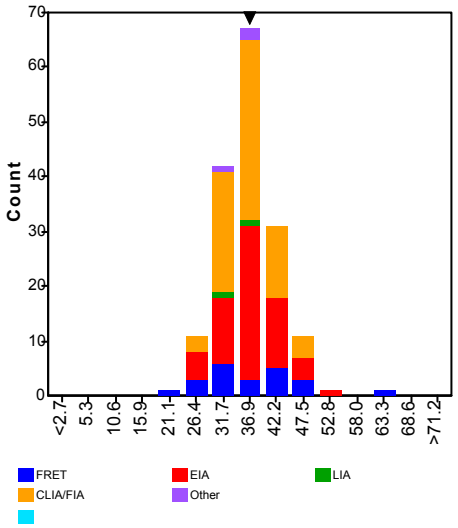
Your Classification Abnormal

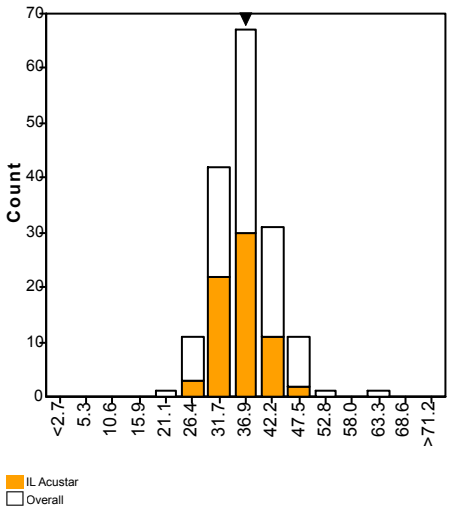
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	165	37	0.49	13.8	19 - 62	35.5	-0.22				
CLIA/FIA	75	36	0.62	11.8	26 - 46	35.5	-0.20				
IL Acustar ADAMTS13 activity	68	36	0.61	11.2	26 - 45	35.5	-0.09				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	165	37	0.49	13.8	19 - 62
FRET	22	37	2.28	23.2	19 - 62
Homemade	10	37	3.54	24.3	26 - 48
Immucor ADAMTS13 activity	4	39			31 - 62
Other	7	39			19 - 46
Sekisui Actifluor ADAMTS13 activity	1	28			-
Enzyme Immuno Assay	63	37	0.84	14.4	25 - 53
Homemade	1	45			-
Other	1	38			-
Technoclone ADAMTS13 acitivity	60	37	0.85	14.4	25 - 53
Technoclone ADAMTS13 activity/antigen	1	40			-
Latex Immuno Assay	2	35			31 - 39
Homemade	1	39			-
Other	1	31			-
CLIA/FIA	75	36	0.62	11.8	26 - 46
Technoclone Technofluor ADAMTS13 ac	7	41			38 - 46
Other	3	35			34 - 36
Homemade	2	35			34 - 35
Other	1	36			-





ADAMTS13 - I

ADAMTS13 Activity

Sample No 23.52
Sample Details Borderline Coagulation Control Plasma
Prior Use None
Unit % or IU/dL
Expiry Date 30-June-2024
Homogeneity 1.7 % **Homogeneity Parameter** APTT
For any method used for the measurement of this parameter with a **CV ≤ 5.7%** 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 161
Number of Responders 150 **Response Rate** 93 %
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:
216 : 11.2%
1086 : 8%
9197 : 16%

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	91	21	15	37	2

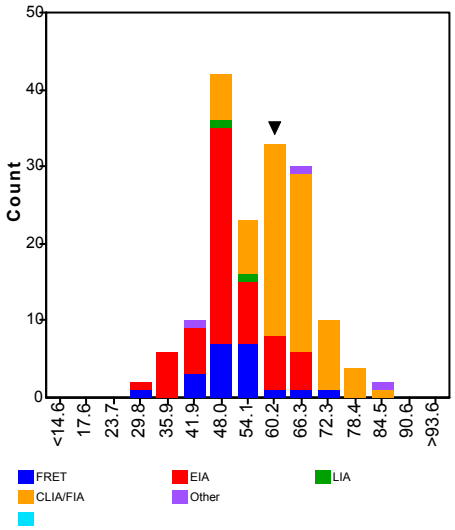
Your Classification Borderline normal

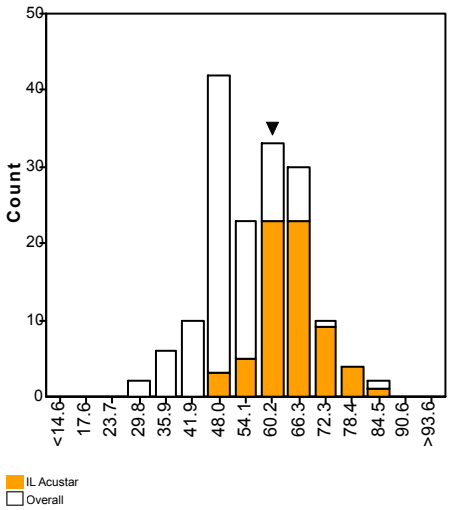
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	162	56	1.08	19.5	27 - 85	61.0	0.44				
CLIA/FIA	75	63	1.10	12.2	46 - 82	61.0	-0.25				
IL Acustar ADAMTS13 activity	68	64	1.05	10.9	46 - 82	61.0	-0.43				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	162	56	1.08	19.5	27 - 85
FRET	21	51	1.93	13.9	27 - 74
Homemade	9	50			40 - 69
Immucor ADAMTS13 activity	4	54			43 - 74
Other	7	51			27 - 57
Sekisui Actifluor ADAMTS13 activity	1	51			-
Enzyme Immuno Assay	61	49	1.38	17.6	31 - 69
Homemade	1	60			-
Other	1	67			-
Technoclone ADAMTS13 acitivity	59	49	1.31	16.6	31 - 69
Latex Immuno Assay	2	50			45 - 54
Homemade	1	45			-
Other	1	54			-
CLIA/FIA	75	63	1.10	12.2	46 - 82
Technoclone Technofluor ADAMTS13 ac	7	52			47 - 58
Other	3	65			43 - 85
Homemade	2	75			65 - 85
Other	1	43			-



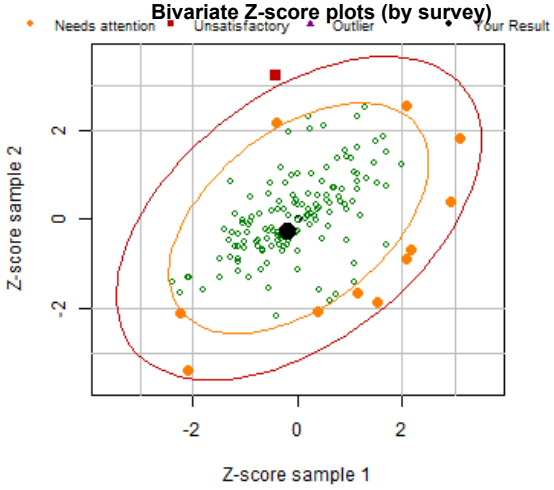


ADAMTS13 - I

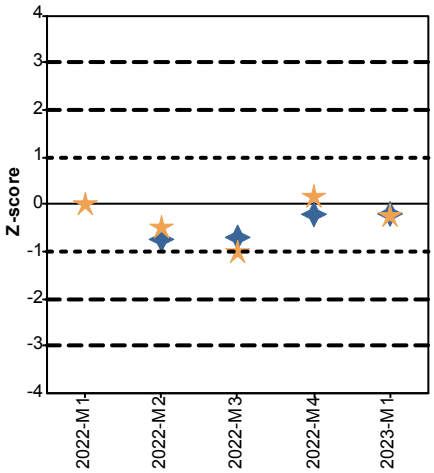
ADAMTS13 Activity

Instrument ID	

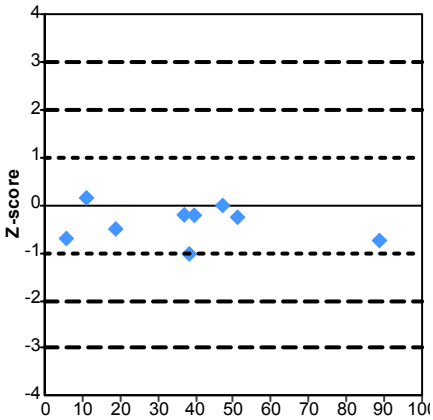
Bivariate Z-score plots (by survey)



Z-score history (by survey)

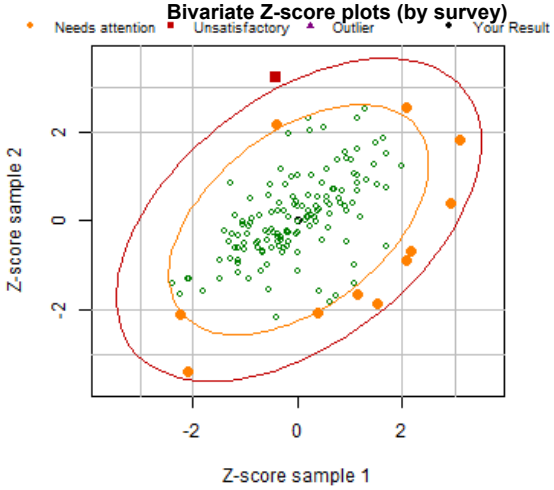


Z-score history (by consensus value)

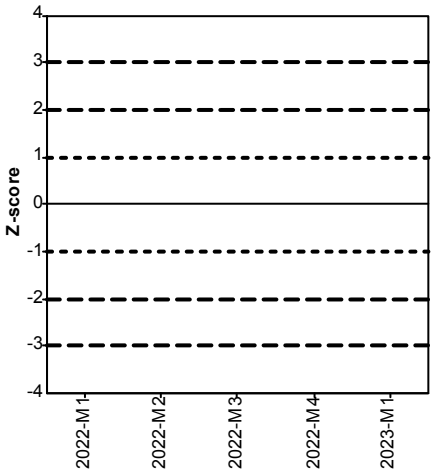


Instrument ID	

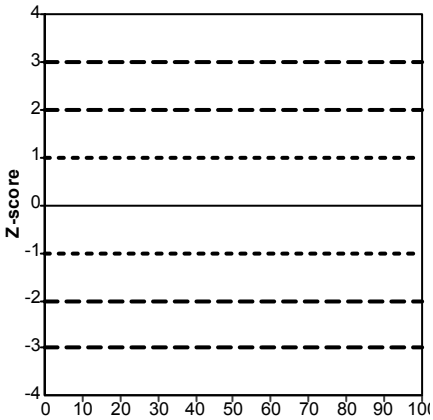
Bivariate Z-score plots (by survey)



Z-score history (by survey)

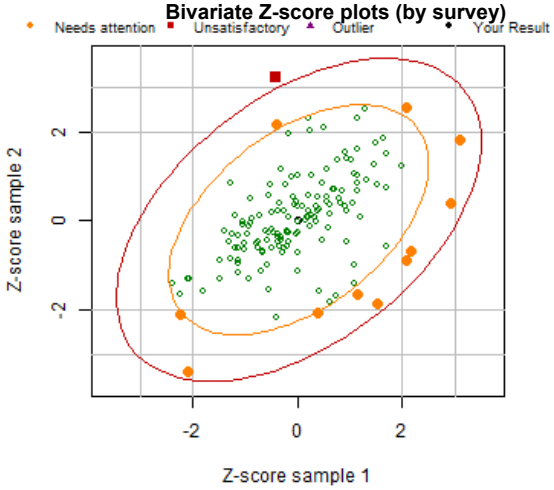


Z-score history (by consensus value)

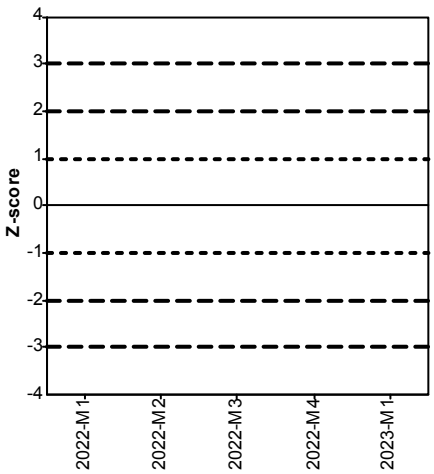


Instrument ID	

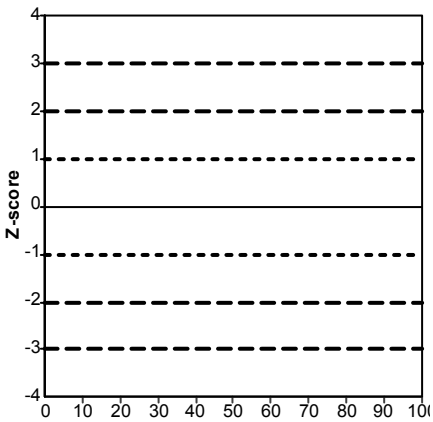
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

ADAMTS13 antigen

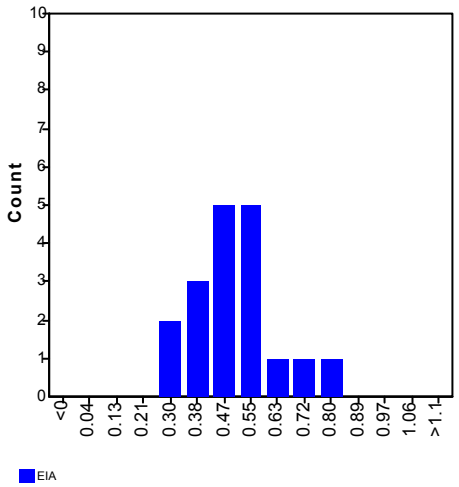
Sample No 23.51
Sample Details Abnormal Coagulation Control Plasma
Prior Use 2022-M4 and 2022-M3
Unit IU/mL
Expiry Date 31-January-2024
Homogeneity 2.4 % **Homogeneity Parameter** APTT
For any method used for the measurement of this parameter with a **CV ≤ 8.0%** the criterion for homogeneity could not 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 161
Number of Responders 19 **Response Rate** 12 %
Comments Two participants (labcode **215** and **950**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

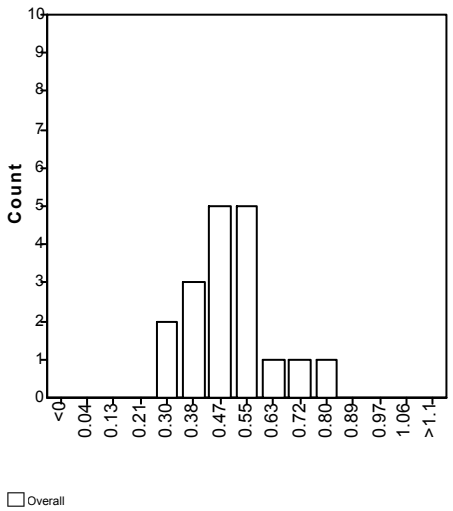
For the most frequently used reagents (n >= 10) the results of sample 23.51 are good comparable with those of sample 22.193 and 22.153 in survey 2022-M4 and 2022-M3.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	12	2	2	4	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	18	0.49	0.04	28.1	0.29 - 0.84
Sekisui Imubind ADAMTS13 antigen	1	0.57			-
Technozym ADAMTS13 activity/antigen	3	0.36			0.30 - 0.38
Technozym ADAMTS13 antigen	14	0.53	0.04	23.1	0.29 - 0.84





ADAMTS13 - I

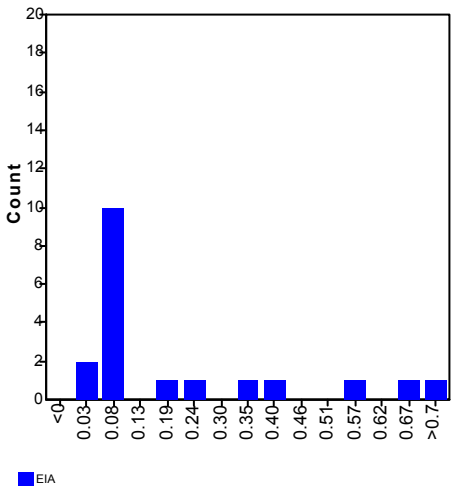
ADAMTS13 antigen

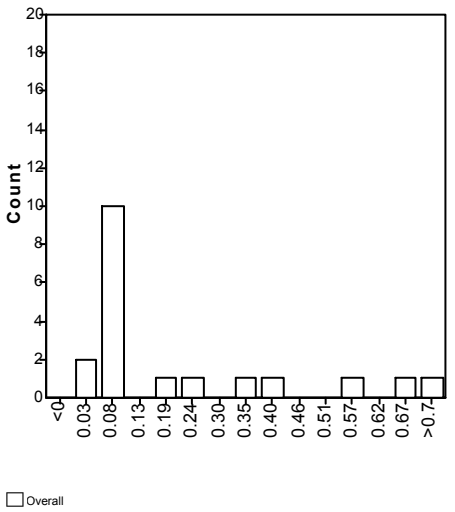
Sample No 23.52
Sample Details Borderline Coagulation Control Plasma
Prior Use None
Unit IU/mL
Expiry Date 30-June-2024
Homogeneity 1.7 % **Homogeneity Parameter** APTT
For any method used for the measurement of this parameter with a **CV ≤ 5.7%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.
Number of Participants 161
Number of Responders 19 **Response Rate** 12 %
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 classificatio
Total	3	1	0	15	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	18	0.15	0.04	96.3	0.05 - 0.70
Sekisui Imubind ADAMTS13 antigen	1	0.07			-
Technozym ADAMTS13 activity/antigen	3	0.10			0.08 - 0.38
Technozym ADAMTS13 antigen	14	0.15	0.05	97.8	0.05 - 0.70



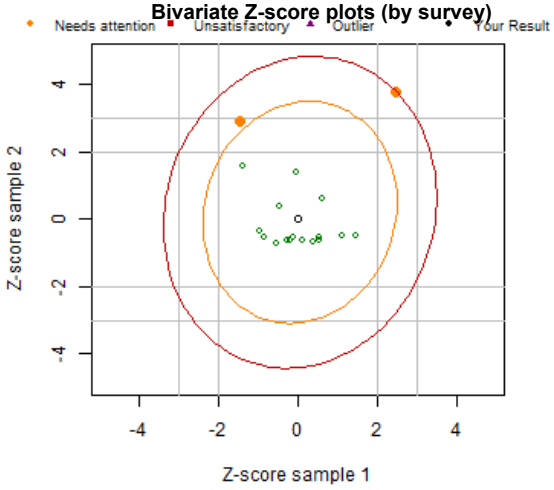


ADAMTS13 - I

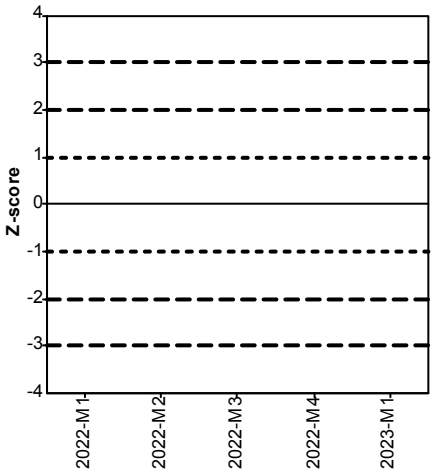
ADAMTS13 antigen

Instrument ID	

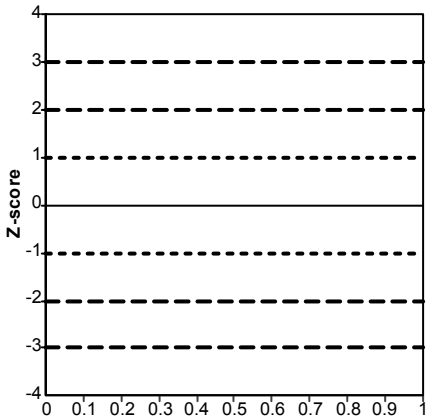
Bivariate Z-score plots (by survey)



Z-score history (by survey)

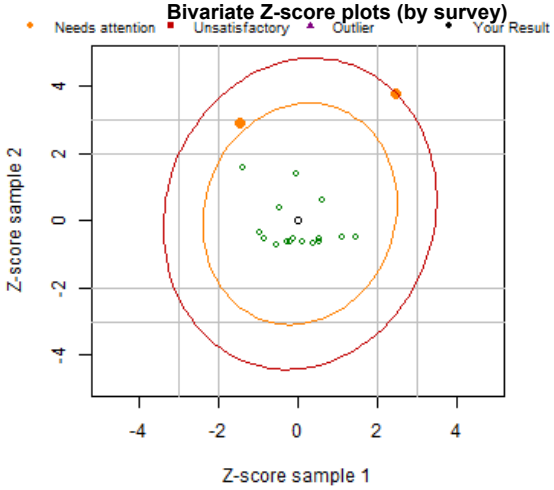


Z-score history (by consensus value)

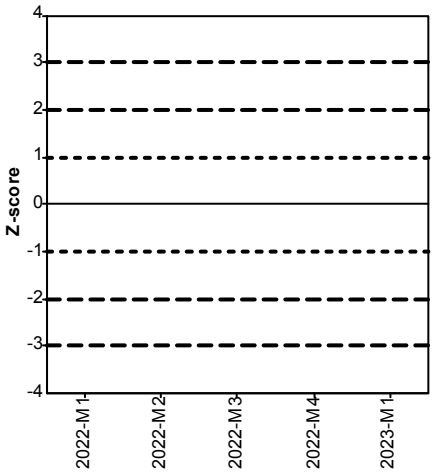


Instrument ID	

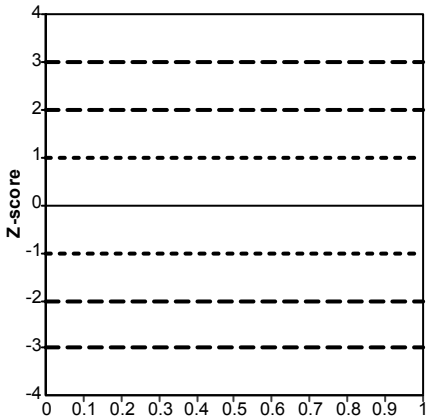
Bivariate Z-score plots (by survey)



Z-score history (by survey)

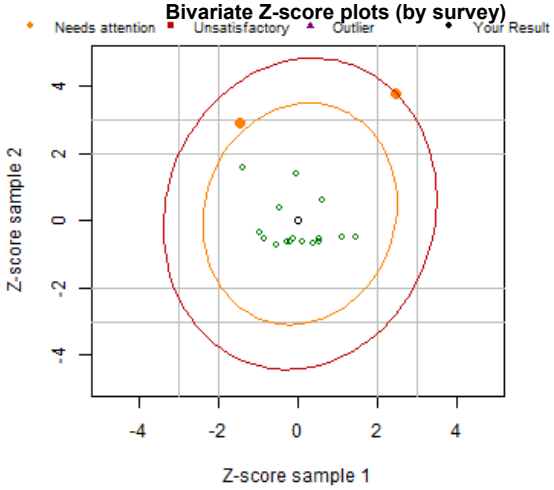


Z-score history (by consensus value)

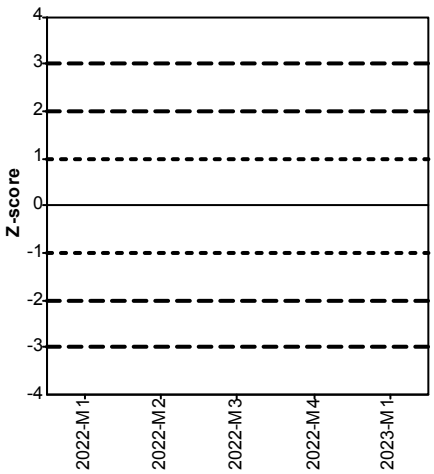
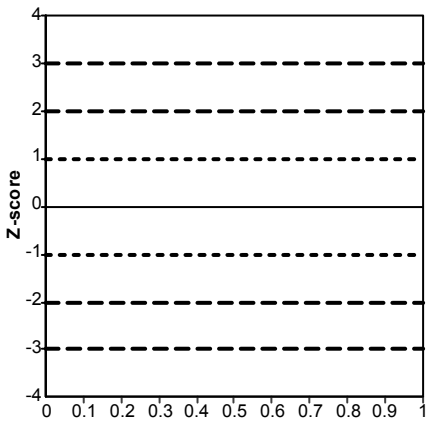


Instrument ID	

Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)