

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-M2

Main

Labcode 1492

Date of Issue : 10-August-2023

Survey : 2023-M2

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 **September 22nd, 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 ($-2 \leq \text{Z-score} \leq 2$)
 UV: Need attention ($-3 < \text{Z-score} < -2$ or $2 < \text{Z-score} < 3$)
 UV:Unsatisfactory ($\text{Z-score} \leq -3$ or ≥ 3)
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
ADAMTS13 - I	ADAMTS13 Activty	23.90	1	0.43	0.62	0.57	
		23.91	1	-0.05	0.47	0.49	

ADAMTS13 - I

ADAMTS13 Activity

Sample No 23.90
Sample Details Normal Coagulation Control Plasma
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2023
Homogeneity 0.6 % **Homogeneity Parameter** APTT
 For any method used for the measurement of this parameter with a CV ≤ 2.0% 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 164
Number of Responders 153 **Response Rate** 93 %
Comments None.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	163	2	0	3	3

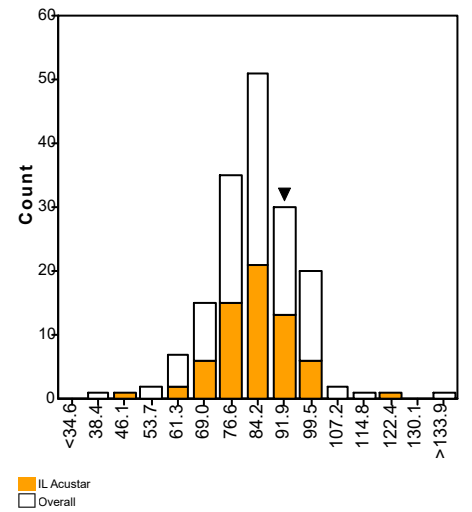
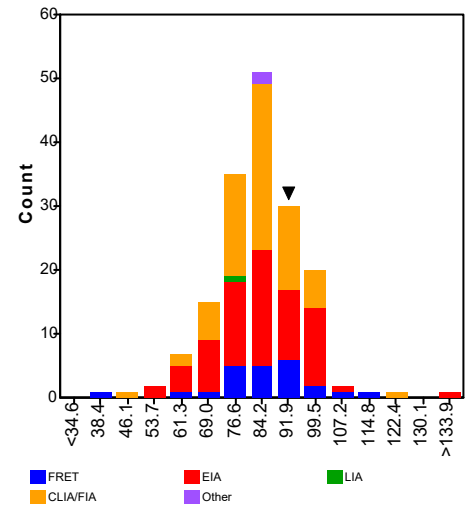
Your Classification Normal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	167	84	1.02	12.6	41 - 176	88.6	0.43				
CLIA/FIA	71	83	1.24	10.1	45 - 120	88.6	0.62				
IL Acustar ADAMTS13 activity	65	83	1.40	10.8	45 - 120	88.6	0.57				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	167	84	1.02	12.6	41 - 176
FRET	23	86	3.14	14.0	41 - 114
Homemade	10	84	6.03	18.1	62 - 114
Immucor ADAMTS13 activity	4	92			86 - 105
Other	8	85			41 - 97
Sekisui Actifluor ADAMTS13 activity	1	93			-
Enzyme Immuno Assay	70	84	1.85	14.7	50 - 176
Homemade	3	66			50 - 70
Other	1	78			-
Technoclone ADAMTS13 activity	65	85	1.76	13.3	58 - 176
Technoclone ADAMTS13 activity/antigen	1	52			-
Latex Immuno Assay	1	76			-
Homemade	1	76			-
CLIA/FIA	71	83	1.24	10.1	45 - 120
Technoclone Technofluor ADAMTS13 ac	6	84			78 - 87
Other	2	86			85 - 86
Homemade	2	86			85 - 86



ADAMTS13 - I	ADAMTS13 Activity
---------------------	--------------------------

Sample No 23.91
Sample Details Plasma with an ADAMTS13 activity level between 10 and 20%
Prior Use None
Unit % or IU/dL
Expiry Date 28-February-2025
Homogeneity 3.7 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 12.3%** 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 164
Number of Responders 153 **Response Rate** 93 %
Comments None.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	0	4	165	3

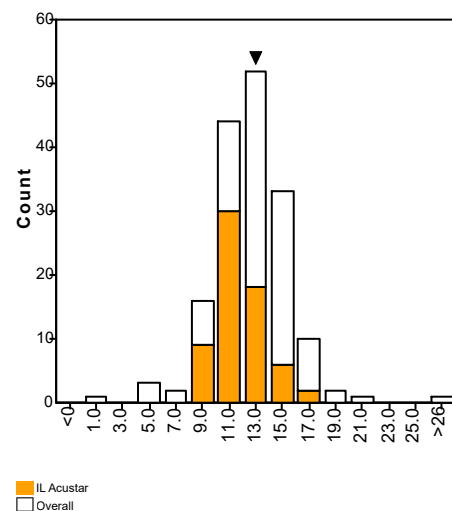
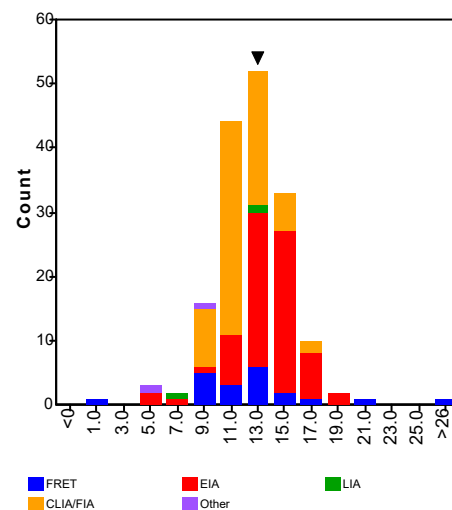
Your Classification Abnormal

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	165	12	0.23	19.0	0 - 32	12.2	-0.05				
CLIA/FIA	71	12	0.22	12.8	8 - 18	12.2	0.47				
IL Acustar ADAMTS13 activity	65	11	0.23	13.1	8 - 18	12.2	0.49				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	165	12	0.23	19.0	0 - 32
FRET	20	12	0.99	30.3	0 - 32
Homemade	7	10			0 - 16
Immucor ADAMTS13 activity	4	14			8 - 32
Other	8	12			8 - 21
Sekisui Actifluor ADAMTS13 activity	1	13			-
Enzyme Immuno Assay	70	13	0.30	15.1	4 - 19
Homemade	2	5.5			4.0 - 7.0
Other	1	13			-
Technoclone ADAMTS13 activity	66	14	0.29	13.9	5 - 19
Technoclone ADAMTS13 activity/antigen	1	9.0			-
Latex Immuno Assay	2	9.2			6.3 - 12.0
Homemade	1	6.3			-
Other	1	12			-
CLIA/FIA	71	12	0.22	12.8	8 - 18
Technoclone Technofluor ADAMTS13 ac	6	12			11 - 13
Other	2	6.5			4.0 - 9.0
Homemade	2	6.5			4.0 - 9.0

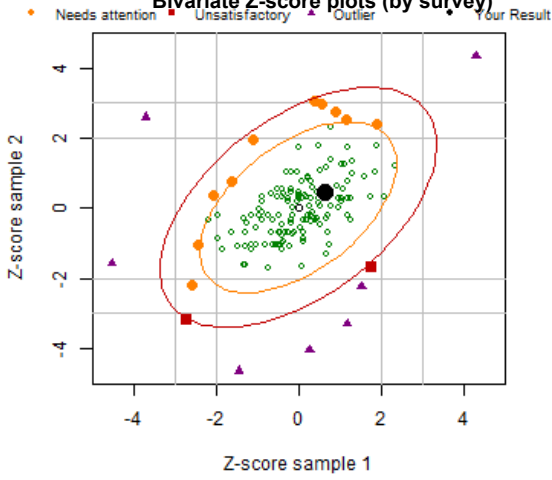


ADAMTS13 - I

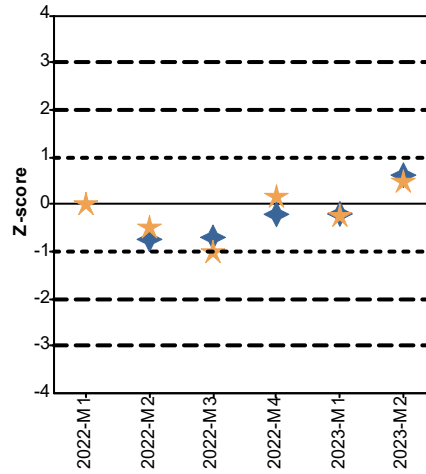
ADAMTS13 Activity

Instrument ID

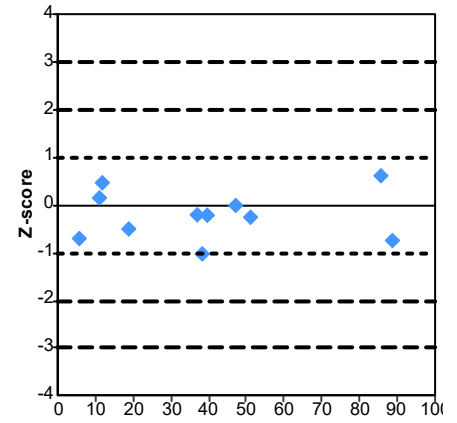
Bivariate Z-score plots (by survey)



Z-score history (by survey)

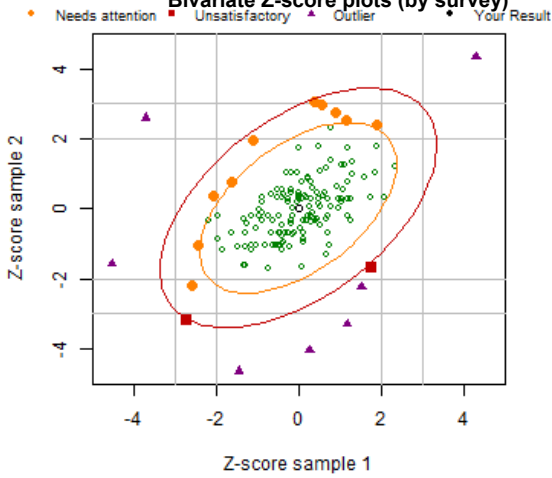


Z-score history (by consensus value)

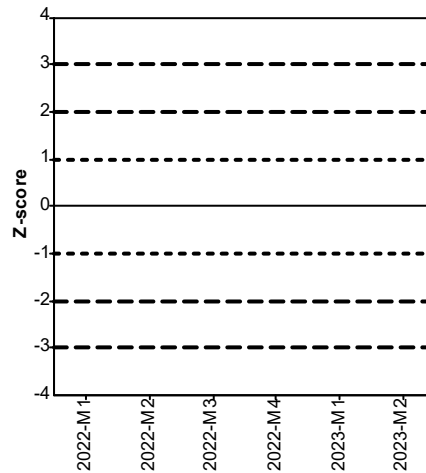


Instrument ID

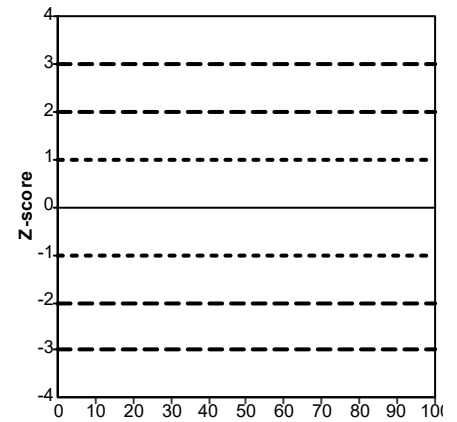
Bivariate Z-score plots (by survey)



Z-score history (by survey)

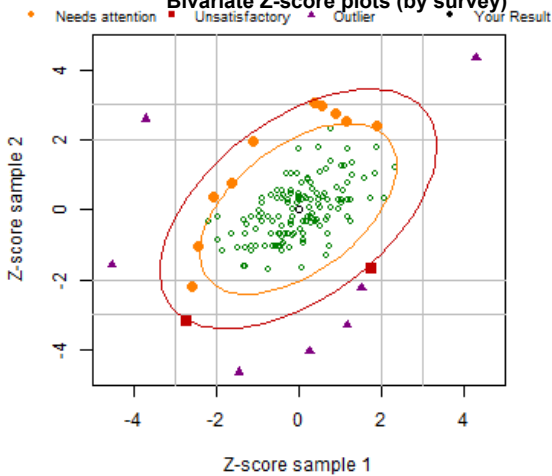


Z-score history (by consensus value)

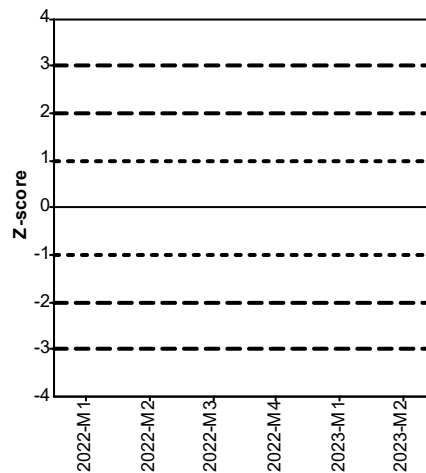


Instrument ID

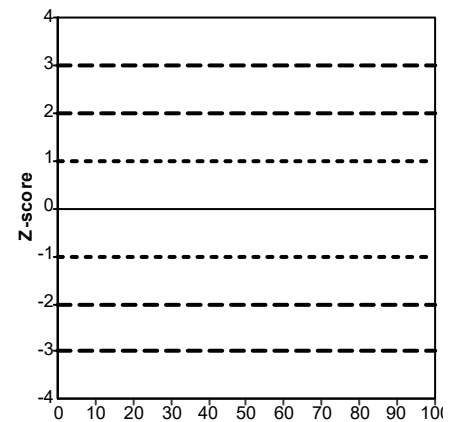
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

ADAMTS13 antigen

Sample No 23.90
Sample Details Normal Coagulation Control Plasma
Prior Use None
Unit IU/mL
Expiry Date 31-December-2023
Homogeneity 0.6 %

Homogeneity Parameter APTT

For any method used for the measurement of this parameter with a CV ≤ 2.0% 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 164
Number of Responders 20

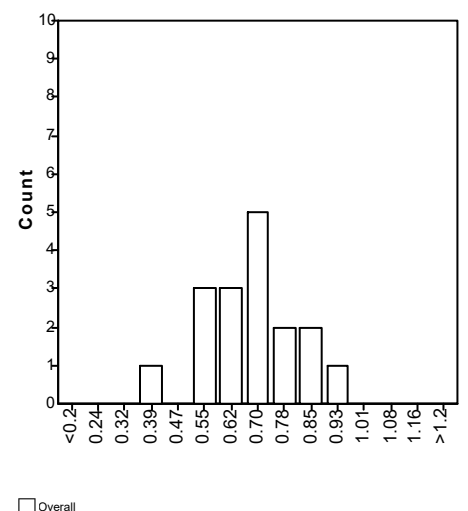
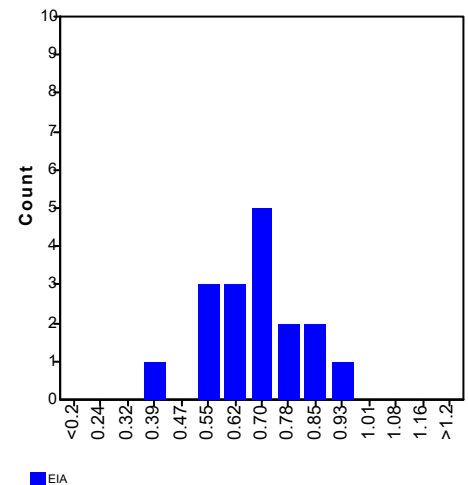
Response Rate 12 %

Comments Two participants (labcodes **1086 and 1196**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	19	1	1	0	0

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	17	0.69	0.04	18.0	0.42 - 0.90
Technozym ADAMTS13 activity/antigen	2	0.62			0.42 - 0.83
Technozym ADAMTS13 antigen	15	0.69	0.03	15.7	0.55 - 0.90



ADAMTS13 - I **ADAMTS13 antigen**

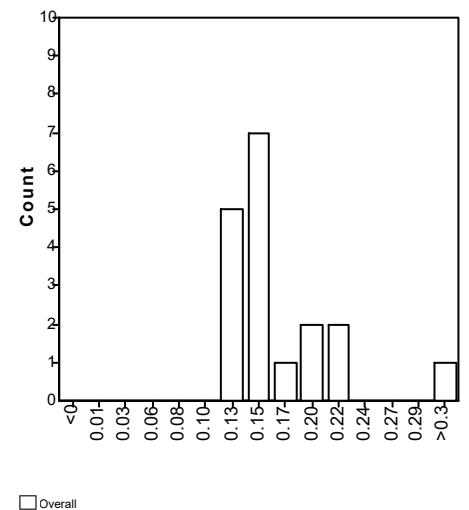
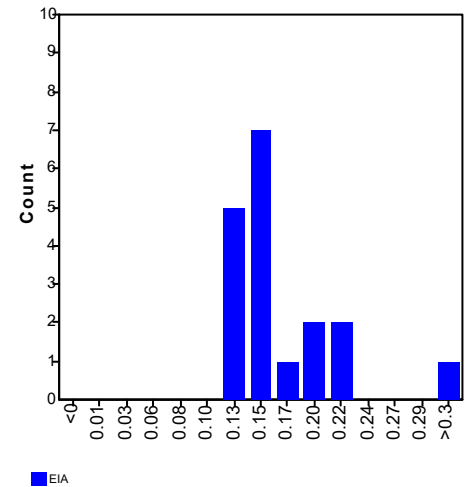
Sample No 23.91
Sample Details Plasma with an ADAMTS13 activity level between 10 and 20%
Prior Use None
Unit IU/mL
Expiry Date 28-February-2025
Homogeneity 3.7 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a CV ≤ 12.3% the criterion for homogeneity 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 164
Number of Responders 20 **Response Rate** 12 %
Comments Two participants (labcodes **1086 and 1196**) selected the wrong unit when submitting the results. These results were excluded in the statistical evaluation.

Classification Overview	Normal	BorderLine normal	Borderline abnormal	Abnormal	No classificatio
Total	0	1	0	20	0

Other Reagents

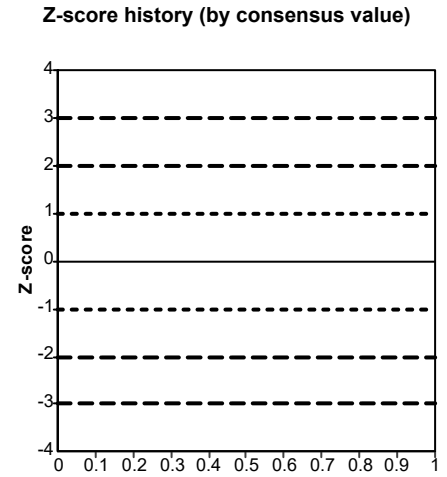
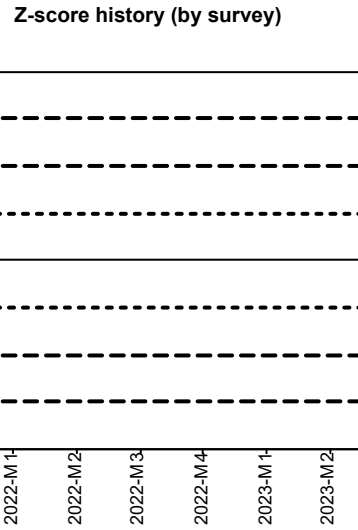
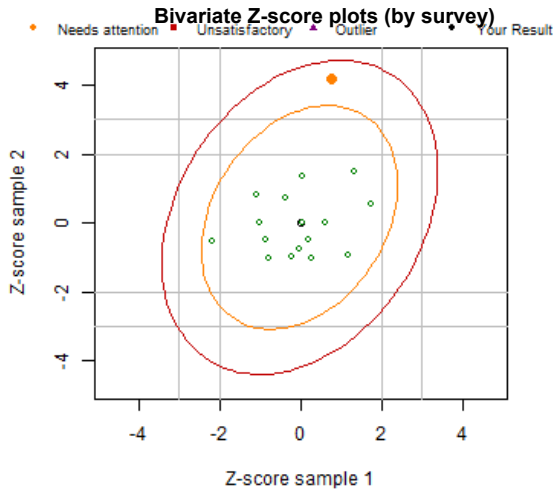
	n	assigned value	Uncert.	CV (%)	Range
Enzyme Immuno Assay	18	0.16	0.01	23.8	0.12 - 0.32
Technozym ADAMTS13 activity/antigen	3	0.14			0.12 - 0.15
Technozym ADAMTS13 antigen	15	0.16	0.01	24.7	0.12 - 0.32



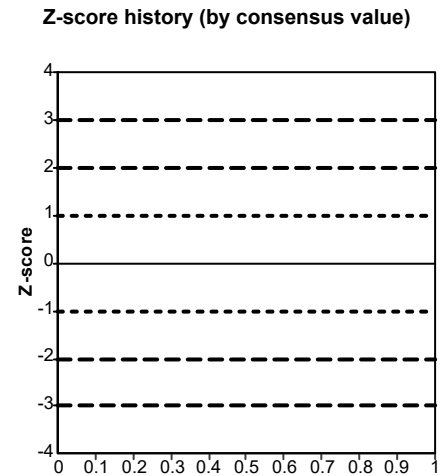
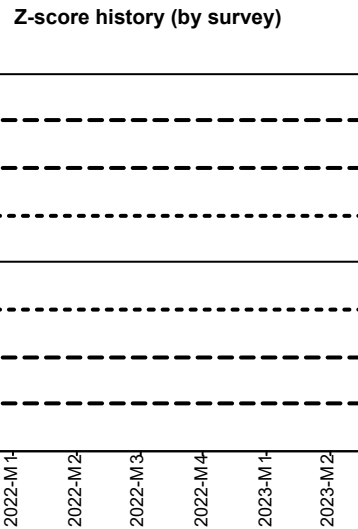
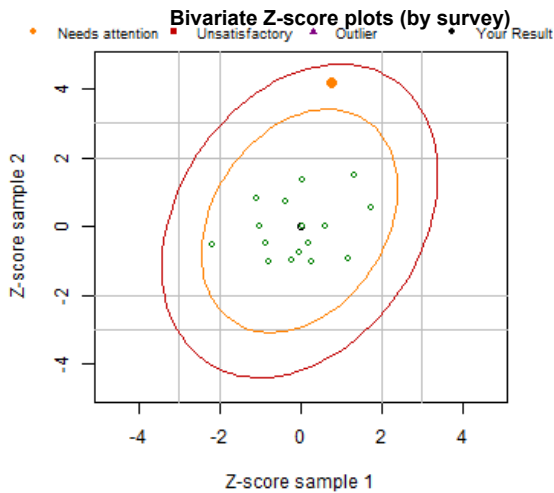
ADAMTS13 - I

ADAMTS13 antigen

Instrument ID



Instrument ID



Instrument ID

