

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-M2

Main

Labcode 1492

Date of Issue : 02-August-2022

Survey : 2022-M2

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 **September 13th, 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, a few participants (labcode **887 & 3828**) 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. P. Meijer
Director

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

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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 | 22.90 | 1 | -0.56 | -0.74 | -0.70 | |
| | | 22.91 | 1 | -0.68 | -0.50 | -0.50 | |

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

Sample No 22.90
Sample Details Normal Coagulation Plasma
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2029
Homogeneity 0.0 % **Homogeneity Parameter** Unknown
Number of Participants 146
Number of Responders 131 **Response Rate** 90 %
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 | 142 | 2 | 0 | 1 | 2 |

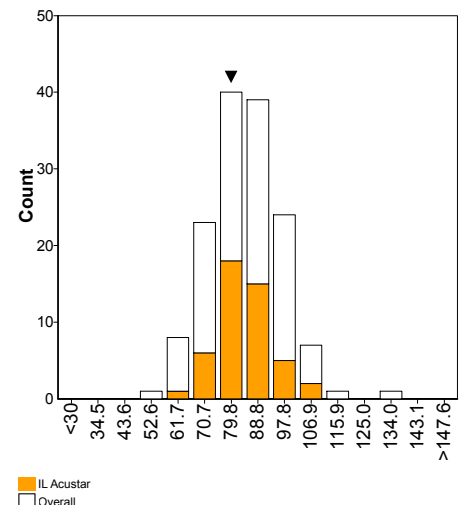
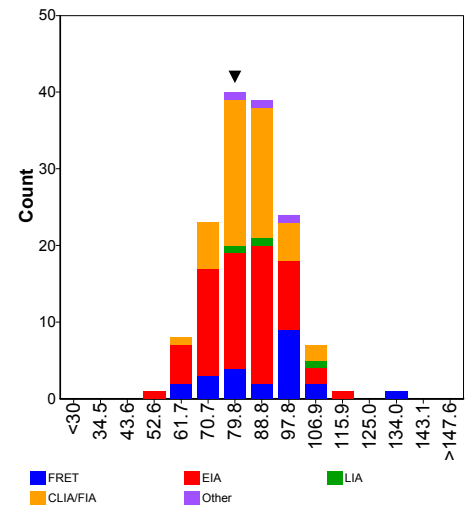
Your Classification Normal

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|-------------------------------------|-----|----------------|---------|--------|----------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 144 | 84 | 1.21 | 13.8 | 57 - 134 | 78 | -0.56 | | | | |
| CLIA/FIA | 50 | 84 | 1.50 | 10.1 | 62 - 105 | 78 | -0.74 | | | | |
| IL Acustar ADAMTS13 activity | 47 | 84 | 1.64 | 10.7 | 62 - 105 | 78 | -0.70 | | | | |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|-----------------------------------------------|-----|----------------|---------|--------|----------|
| Total Group | 144 | 84 | 1.21 | 13.8 | 57 - 134 |
| FRET | 23 | 89 | 3.83 | 16.6 | 58 - 134 |
| Homemade | 10 | 94 | 4.18 | 11.3 | 72 - 104 |
| Immucor ADAMTS13 activity | 3 | 77 | | | 71 - 95 |
| Other | 9 | 89 | | | 58 - 134 |
| Sekisui Actifluor ADAMTS13 activity | 1 | 100 | | | - |
| Enzyme Immuno Assay | 65 | 82 | 1.90 | 14.9 | 57 - 117 |
| Homemade | 3 | 80 | | | 71 - 95 |
| Other | 1 | 75 | | | - |
| Technoclone ADAMTS13 activity | 60 | 83 | 1.96 | 14.7 | 63 - 117 |
| Technoclone ADAMTS13 activity/antigen | 1 | 57 | | | - |
| Latex Immuno Assay | 3 | 93 | | | 83 - 111 |
| Homemade | 2 | 88 | | | 83 - 93 |
| Other | 1 | 111 | | | - |
| CLIA/FIA | 50 | 84 | 1.50 | 10.1 | 62 - 105 |
| Technoclone Technofluor ADAMTS13 activ | 3 | 85 | | | 83 - 88 |
| Other | 3 | 89 | | | 79 - 94 |
| Homemade | 2 | 92 | | | 89 - 94 |
| Other | 1 | 79 | | | - |



ADAMTS13 - I

ADAMTS13 Activity

Sample No 22.91
Sample Details Plasma with an ADAMTS13 activity level between 10 and 30%
Prior Use None
Unit % or IU/dL
Expiry Date 31-December-2023
Homogeneity 4.3 % **Homogeneity Parameter** ADAMTS13
 For any method used for the measurement of this parameter with a **CV ≤ 14.3%** 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 146
Number of Responders 131 **Response Rate** 90 %
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 | 0 | 1 | 10 | 133 | 3 |

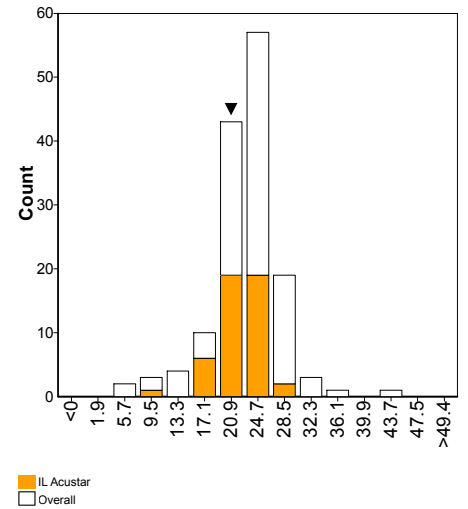
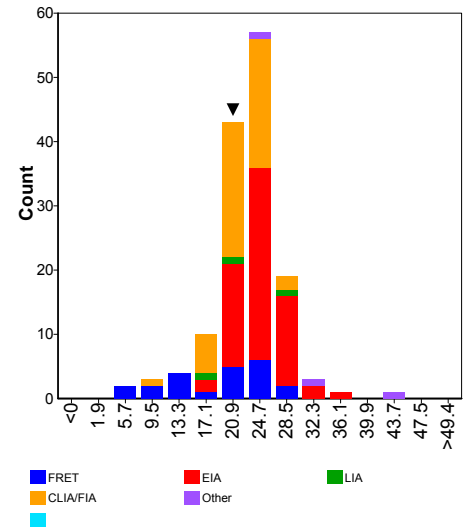
Your Classification Borderline abnormal

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|------------------------------|-----|----------------|---------|--------|---------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 143 | 23 | 0.40 | 16.3 | 6 - 45 | 20.6 | -0.68 | | | | |
| CLIA/FIA | 50 | 22 | 0.50 | 12.8 | 11 - 30 | 20.6 | -0.50 | | | | |
| IL Acustar ADAMTS13 activity | 47 | 22 | 0.53 | 13.1 | 11 - 30 | 20.6 | -0.50 | | | | |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|----------------------------------------|-----|----------------|---------|--------|---------|
| Total Group | 143 | 23 | 0.40 | 16.3 | 6 - 45 |
| FRET | 22 | 19 | 2.04 | 40.8 | 6 - 29 |
| Homemade | 9 | 21 | | | 12 - 29 |
| Immucor ADAMTS13 activity | 3 | 15 | | | 6 - 21 |
| Other | 9 | 22 | | | 6 - 26 |
| Sekisui Actifluor ADAMTS13 activity | 1 | 28 | | | - |
| Enzyme Immuno Assay | 65 | 25 | 0.47 | 12.3 | 18 - 35 |
| Homemade | 2 | 23 | | | 20 - 25 |
| Other | 1 | 21 | | | - |
| Technoclone ADAMTS13 activity | 61 | 25 | 0.46 | 11.6 | 18 - 35 |
| Technoclone ADAMTS13 activity/antigen | 1 | 18 | | | - |
| Latex Immuno Assay | 3 | 21 | | | 17 - 29 |
| Homemade | 2 | 19 | | | 17 - 21 |
| Other | 1 | 29 | | | - |
| CLIA/FIA | 50 | 22 | 0.50 | 12.8 | 11 - 30 |
| Technoclone Technofluor ADAMTS13 activ | 3 | 22 | | | 19 - 23 |
| Other | 3 | 34 | | | 26 - 45 |
| Homemade | 2 | 40 | | | 34 - 45 |
| Other | 1 | 26 | | | - |



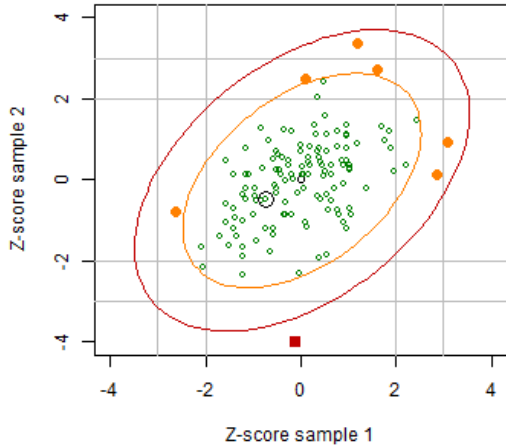
ADAMTS13 - I

ADAMTS13 Activity

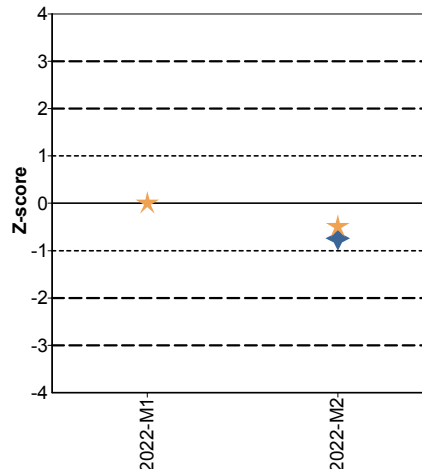
Instrument ID

Bivariate Z-score plots (by survey)

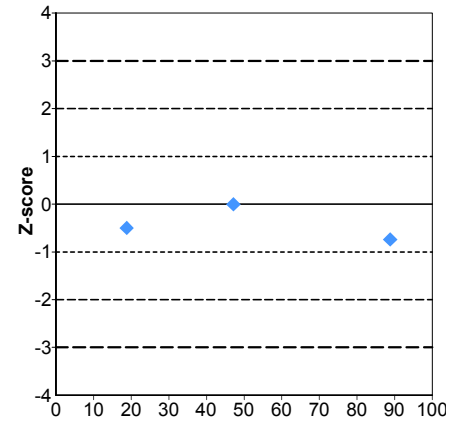
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



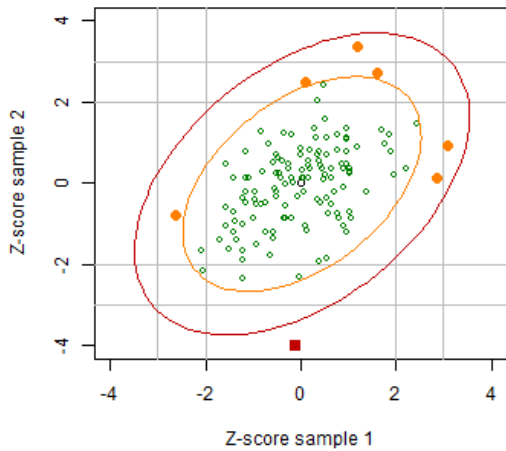
Z-score history (by consensus value)



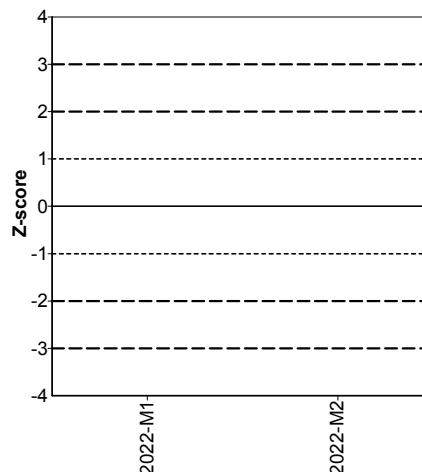
Instrument ID

Bivariate Z-score plots (by survey)

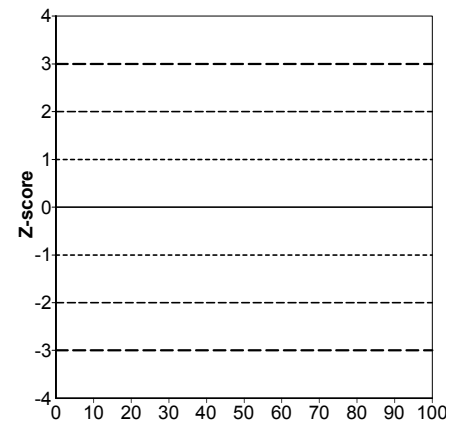
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



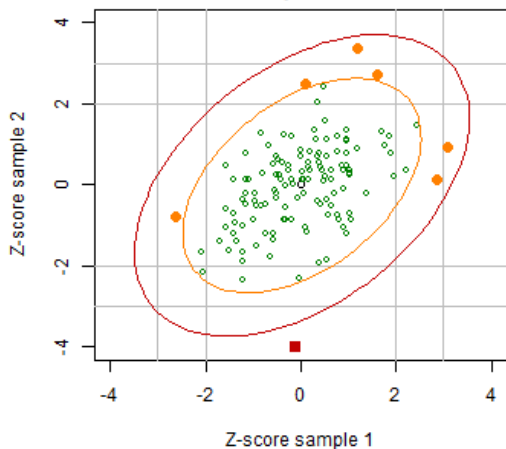
Z-score history (by consensus value)



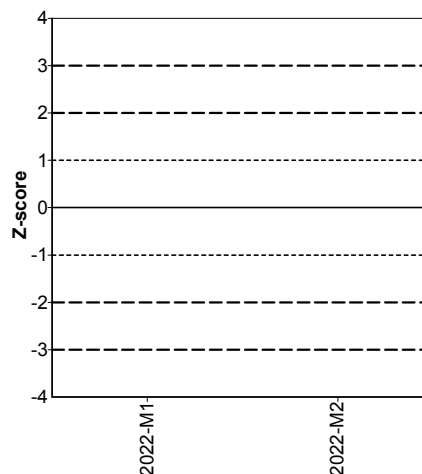
Instrument ID

Bivariate Z-score plots (by survey)

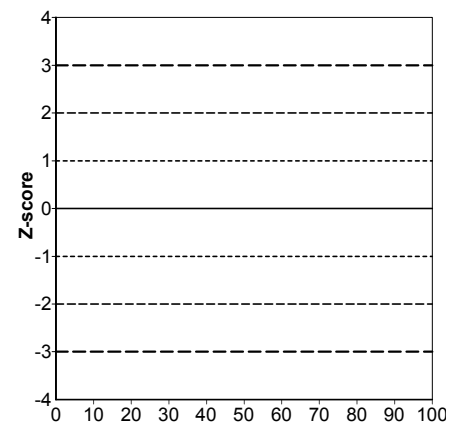
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



Z-score history (by consensus value)



ADAMTS13 - I

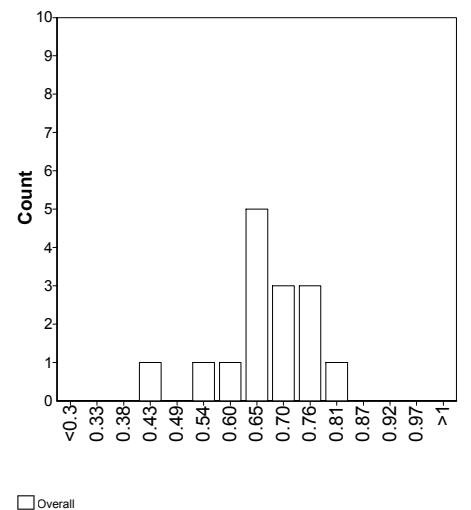
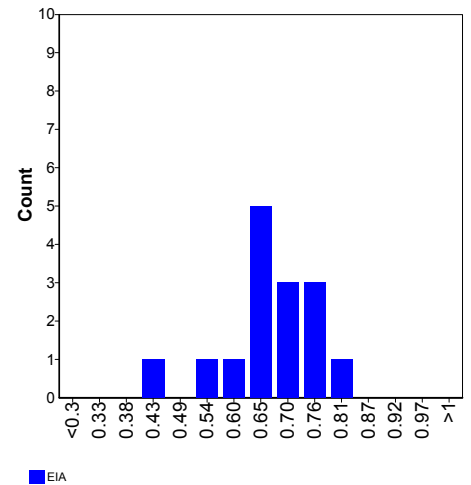
ADAMTS13 antigen

| | | | |
|-------------------------------|---------------------------|------------------------------|---------|
| Sample No | 22.90 | | |
| Sample Details | Normal Coagulation Plasma | | |
| Prior Use | None | | |
| Unit | IU/mL | | |
| Expiry Date | 31-December-2029 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | Unknown |
| Number of Participants | 146 | | |
| Number of Responders | 15 | Response Rate | 10 % |
| Comments | None | | |

| Classification Overview | Normal | BorderLine normal | Borderline abnormal | Abnormal | No classification |
|-------------------------|--------|-------------------|---------------------|----------|-------------------|
| Total | 15 | 0 | 0 | 0 | 0 |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|--------------------------------------------|----|----------------|---------|--------|-------------|
| Enzyme Immuno Assay | 15 | 0.67 | 0.03 | 12.5 | 0.45 - 0.83 |
| Technozym ADAMTS13 activity/antigen | 4 | 0.62 | | | 0.56 - 0.83 |
| Technozym ADAMTS13 antigen | 11 | 0.68 | 0.02 | 9.6 | 0.45 - 0.77 |



ADAMTS13 - I

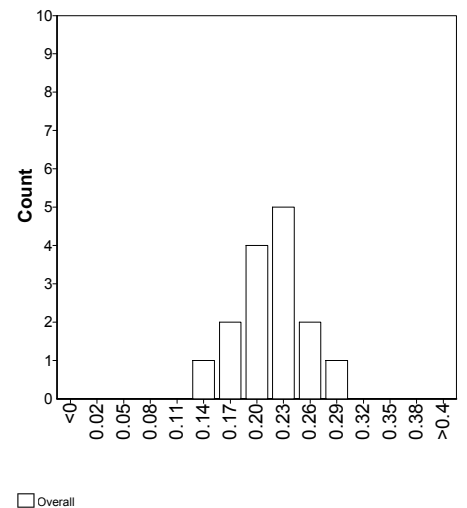
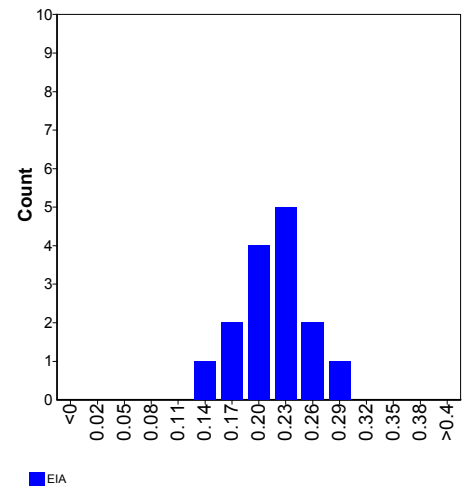
ADAMTS13 antigen

| | | | |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------|
| Sample No | 22.91 | | |
| Sample Details | Plasma with an ADAMTS13 activity level between 10 and 30% | | |
| Prior Use | None | | |
| Unit | IU/mL | | |
| Expiry Date | 31-December-2023 | | |
| Homogeneity | 4.3 % | Homogeneity Parameter | ADAMTS13 |
| | For any method used for the measurement of this parameter with a CV ≤ 14.3% 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 | 146 | | |
| Number of Responders | 15 | Response Rate | 10 % |
| Comments | None | | |

| Classification Overview | Normal | BorderLine normal | Borderline abnormal | Abnormal | No classification |
|-------------------------|--------|-------------------|---------------------|----------|-------------------|
| Total | 0 | 1 | 0 | 14 | 0 |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|-------------------------------------|----|----------------|---------|--------|-------------|
| Enzyme Immuno Assay | 15 | 0.21 | 0.01 | 19.8 | 0.14 - 0.28 |
| Technozym ADAMTS13 activity/antigen | 4 | 0.18 | | | 0.14 - 0.24 |
| Technozym ADAMTS13 antigen | 11 | 0.22 | 0.01 | 16.3 | 0.18 - 0.28 |

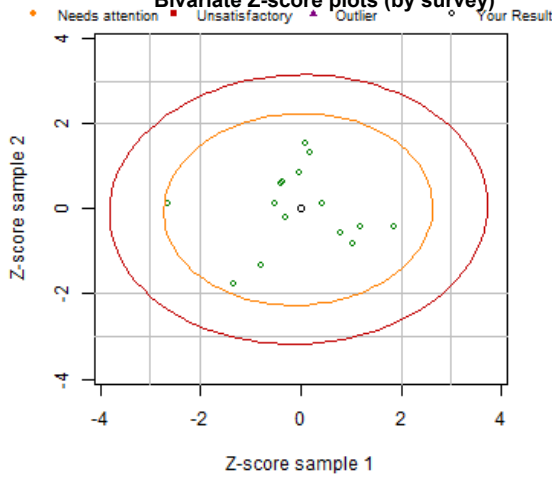


ADAMTS13 - I

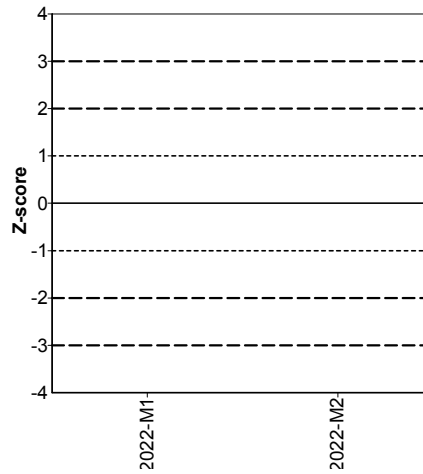
ADAMTS13 antigen

Instrument ID

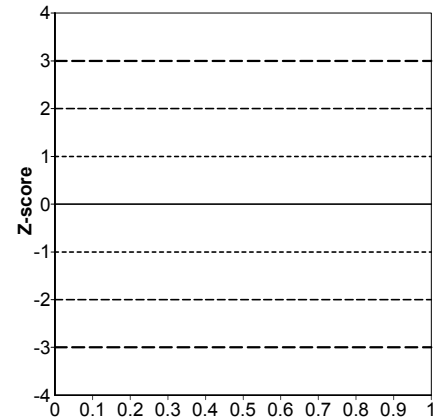
Bivariate Z-score plots (by survey)



Z-score history (by survey)

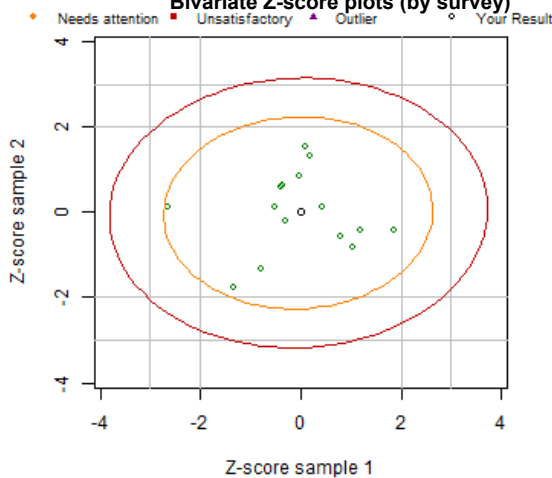


Z-score history (by consensus value)

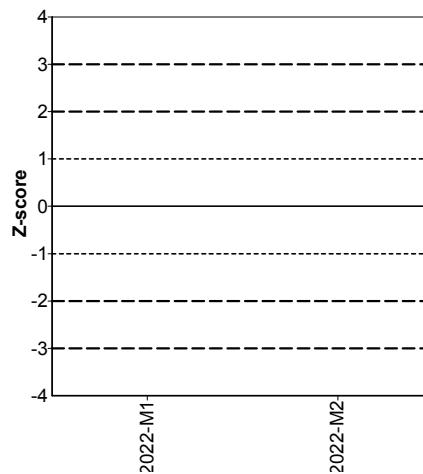


Instrument ID

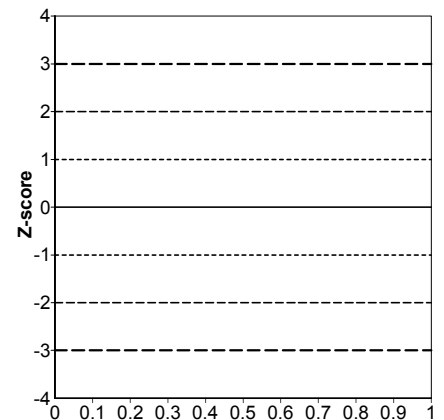
Bivariate Z-score plots (by survey)



Z-score history (by survey)

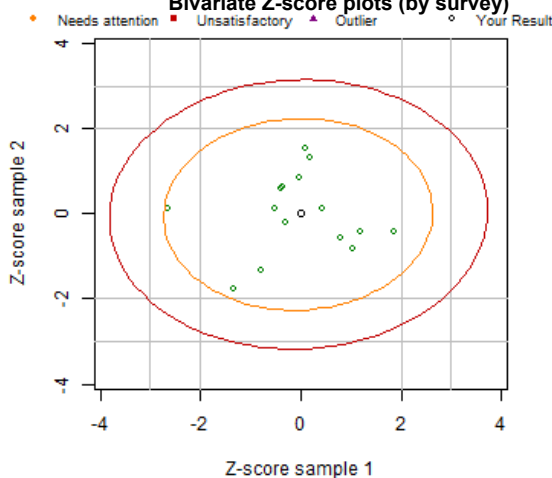


Z-score history (by consensus value)

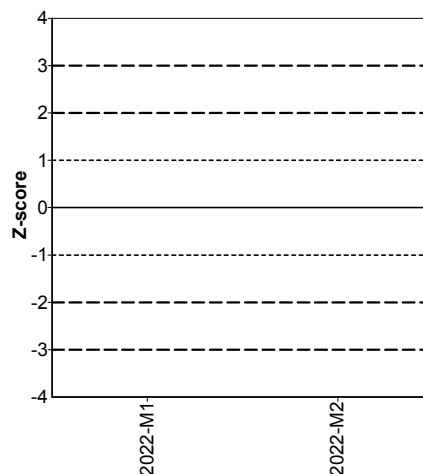


Instrument ID

Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)

