

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2022-M1**

**Main**

**Labcode 1492**

Date of Issue : 20-May-2022

Survey : 2022-M1

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 **July 1st, 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. 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 .

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Appendices are an integral part of the total report.

**OVERVIEW Z-SCORES**

UV:Satisfactory ( $-2 \leq Z\text{-score} \leq 2$ )  
 BV: Acceptable
  UV: Need attention ( $-3 < Z\text{-score} < -2$  or  $2 < Z\text{-score} < 3$ )  
 BV: Questionable
  UV:Unsatisfactory ( $Z\text{-score} \leq -3$  or  $\geq 3$ )  
 BV: Unacceptable

| Module       | Parameter                        | Sample | Test System | Total | Assay | Method | Bivariate Analysis |  |
|--------------|----------------------------------|--------|-------------|-------|-------|--------|--------------------|--|
|              |                                  |        |             |       |       |        |                    |  |
| ADAMTS13 - I | ADAMTS13 Activity/antigen Adam 1 | 22.52  | 1           | 0.86  | 0.00  | -0.08  |                    |  |

|                     |                          |
|---------------------|--------------------------|
| <b>ADAMTS13 - I</b> | <b>ADAMTS13 Activity</b> |
|---------------------|--------------------------|

**Sample No** 22.51  
**Sample Details** Plasma with an ADAMTS13 activity level <5%  
**Prior Use** Prior Use: None  
**Unit** % or IU/dL  
**Expiry Date** 31-January-2024  
**Homogeneity** 0.0 % **Homogeneity Parameter** ADAMTS13  
**Number of Participants** 143  
**Number of Responders** 129 **Response Rate** 90 %  
**Comments** Participant **1487** reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the sample 22.51 and 22.52.

The CV of the method group CLIA/FIA and the method IL Acustar ADAMTS13 activity is below 0.1, which could result in a large Z-score when deviating a relatively small distance from the assigned value. Therefore, the Z-score should be interpret with caution, since it might be clinically not significant.

| Classification Overview | Normal | BorderLine normal | Borderline abnormal | Abnormal | No classification |
|-------------------------|--------|-------------------|---------------------|----------|-------------------|
| <b>Total</b>            | 3      | 0                 | 0                   | 138      | 2                 |

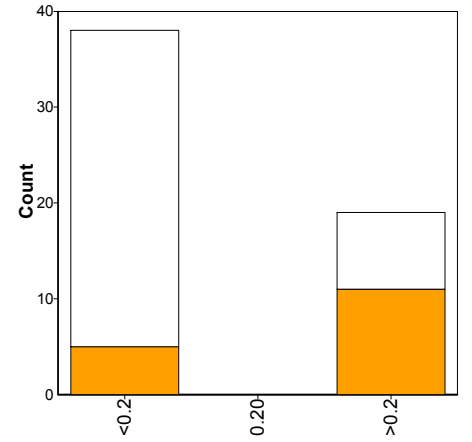
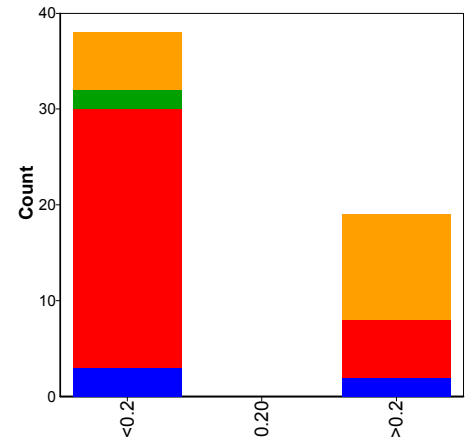
**Your Classification** Abnormal

**Own Reagent**

|                                     | n  | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|-------------------------------------|----|----------------|---------|--------|-------|-------------|---------|-------------|---------|-------------|---------|
| <b>Total Group</b>                  | 57 | 0              |         |        | 0 - 7 | < 0.2       |         |             |         |             |         |
| <b>CLIA/FIA</b>                     | 17 | 0              | 0.00    | 0.0    | 0 - 1 | < 0.2       |         |             |         |             |         |
| <b>IL Acustar ADAMTS13 activity</b> | 16 | 0              | 0.00    | 0.0    | 0 - 1 | < 0.2       |         |             |         |             |         |

**Other Reagents**

|   | n  | assigned value | Uncert. | CV (%) | Range |
|---|----|----------------|---------|--------|-------|
| <b>Total Group</b>                            | 57 | 0              |         |        | 0 - 7 |
| <b>FRET</b>                                   | 5  | 0              |         |        | 0 - 7 |
| <b>Homemade</b>                               | 2  | 2              |         |        | 0 - 3 |
| <b>Other</b>                                  | 2  | 0              |         |        | 0 - 0 |
| <b>Sekisui Actifluor ADAMTS13 activity</b>    | 1  | 7              |         |        | -     |
| <b>Enzyme Immuno Assay</b>                    | 33 | 0              |         |        | 0 - 3 |
| <b>Homemade</b>                               | 1  | 2              |         |        | -     |
| <b>Other</b>                                  | 2  | 0              |         |        | 0 - 0 |
| <b>Technoclone ADAMTS13 acitivity</b>         | 29 | 0              |         |        | 0 - 3 |
| <b>Technoclone ADAMTS13 activity/antigen</b>  | 1  | 0              |         |        | -     |
| <b>Latex Immuno Assay</b>                     | 2  | 0              |         |        | 0 - 0 |
| <b>Homemade</b>                               | 2  | 0              |         |        | 0 - 0 |
| <b>CLIA/FIA</b>                               | 17 | 0              | 0.00    | 0.0    | 0 - 1 |
| <b>Technoclone Technofluor ADAMTS13 activ</b> | 1  | 0              |         |        | -     |



**ADAMTS13 - I**

**ADAMTS13 Activity**

**Sample No** 22.52  
**Sample Details** Borderline Coagulation Control Plasma  
**Prior Use** Prior Use: None  
**Unit** % or IU/dL  
**Expiry Date** 31-December-2022  
**Homogeneity** 1.5 % **Homogeneity Parameter** APTT  
 For any method used for the measurement of this parameter with a CV ≤ 5.0% 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** 143  
**Number of Responders** 129 **Response Rate** 90 %  
**Comments** Participant **1487** reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the sample 22.51 and 22.52.

| Classification Overview | Normal | BorderLine normal | Borderline abnormal | Abnormal | No classification |
|-------------------------|--------|-------------------|---------------------|----------|-------------------|
| <b>Total</b>            | 70     | 18                | 30                  | 23       | 2                 |

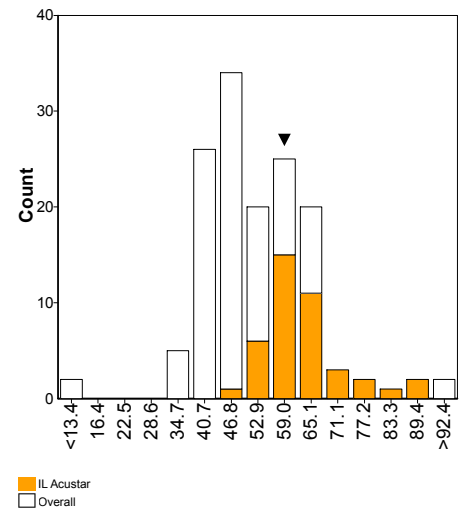
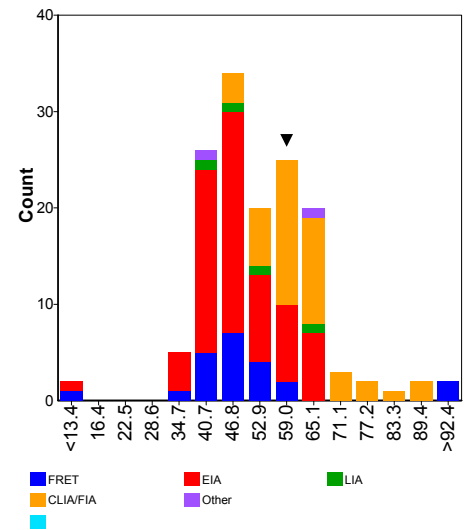
Your Classification Normal

**Own Reagent**

|                              | n   | assigned value | Uncert. | CV (%) | Range    |             |         |             |         |             |         |
|------------------------------|-----|----------------|---------|--------|----------|-------------|---------|-------------|---------|-------------|---------|
|                              |     |                |         |        |          | your result | z-score | your result | z-score | your result | z-score |
| <b>Total Group</b>           | 142 | 52             | 1.17    | 21.4   | 10 - 104 | 62.0        | 0.86    |             |         |             |         |
| <b>CLIA/FIA</b>              | 43  | 62             | 1.45    | 12.2   | 48 - 90  | 62.0        | 0.00    |             |         |             |         |
| IL Acustar ADAMTS13 activity | 41  | 63             | 1.38    | 11.3   | 49 - 90  | 62.0        | -0.08   |             |         |             |         |

**Other Reagents**

|  | n   | assigned value | Uncert. | CV (%) | Range    |
|--|-----|----------------|---------|--------|----------|
| <b>Total Group</b>                     | 142 | 52             | 1.17    | 21.4   | 10 - 104 |
| <b>FRET</b>                            | 22  | 47             | 2.19    | 17.4   | 10 - 104 |
| Homemade                               | 10  | 42             | 3.25    | 19.5   | 10 - 56  |
| Immucor ADAMTS13 activity              | 2   | 49             |         |        | 45 - 53  |
| Other                                  | 9   | 48             |         |        | 43 - 104 |
| Sekisui Actifluor ADAMTS13 activity    | 1   | 57             |         |        | -        |
| <b>Enzyme Immuno Assay</b>             | 71  | 48             | 1.28    | 18.0   | 12 - 66  |
| Homemade                               | 2   | 37             |         |        | 34 - 40  |
| Other                                  | 3   | 61             |         |        | 60 - 64  |
| Technoclone ADAMTS13 activity          | 65  | 48             | 1.14    | 15.5   | 34 - 66  |
| Technoclone ADAMTS13 activity/antigen  | 1   | 12             |         |        | -        |
| <b>Latex Immuno Assay</b>              | 4   | 49             |         |        | 42 - 67  |
| Homemade                               | 3   | 45             |         |        | 42 - 52  |
| Other                                  | 1   | 67             |         |        | -        |
| <b>CLIA/FIA</b>                        | 43  | 62             | 1.45    | 12.2   | 48 - 90  |
| Technoclone Technofluor ADAMTS13 activ | 2   | 48             |         |        | 48 - 49  |
| Other                                  | 2   | 55             |         |        | 42 - 68  |
| Homemade                               | 1   | 68             |         |        | -        |
| Other                                  | 1   | 42             |         |        | -        |



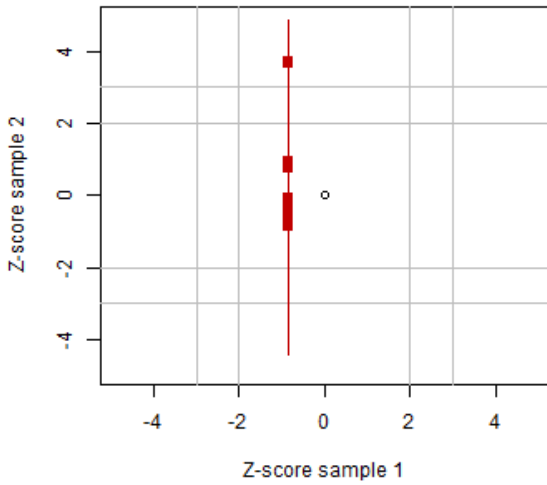
ADAMTS13 - I

ADAMTS13 Activity

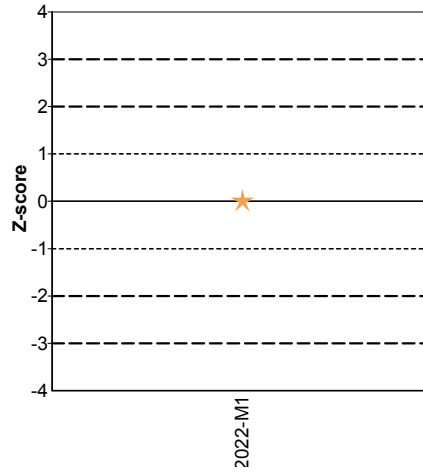
Instrument ID

Bivariate Z-score plots (by survey)

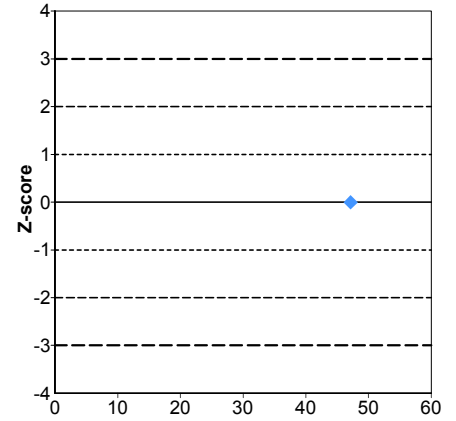
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



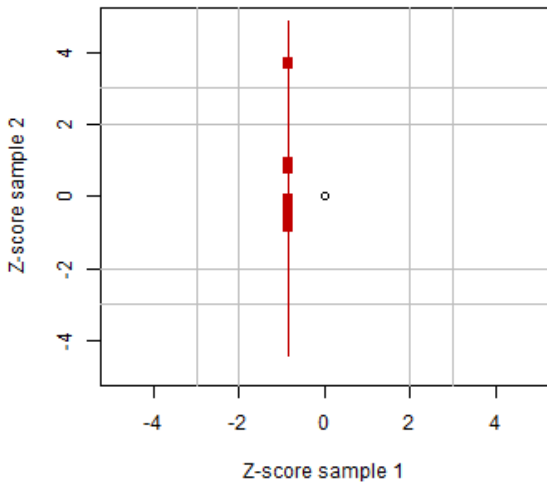
Z-score history (by consensus value)



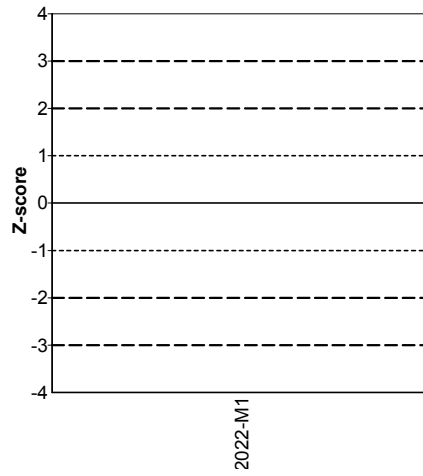
Instrument ID

Bivariate Z-score plots (by survey)

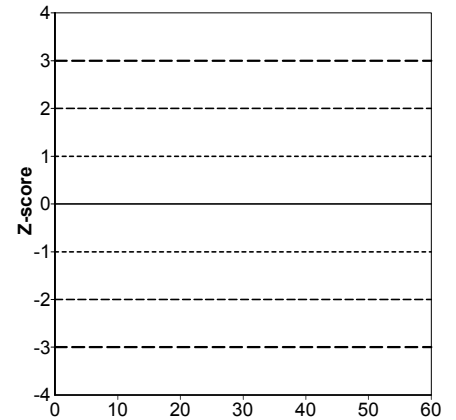
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



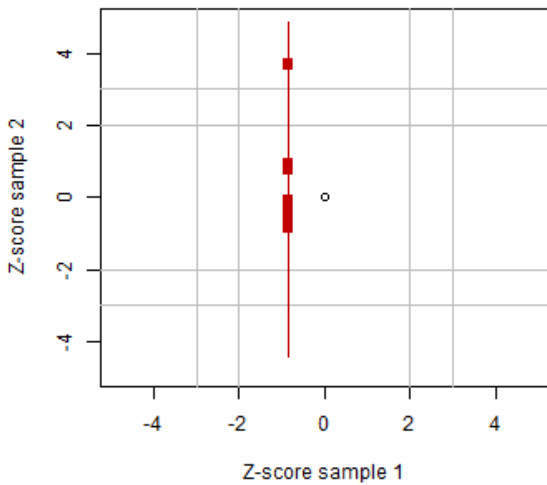
Z-score history (by consensus value)



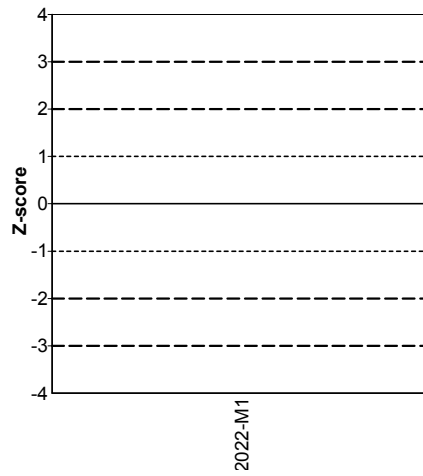
Instrument ID

Bivariate Z-score plots (by survey)

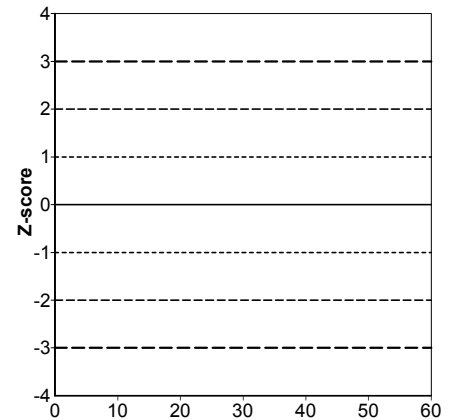
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



Z-score history (by consensus value)





**ADAMTS13 - I**

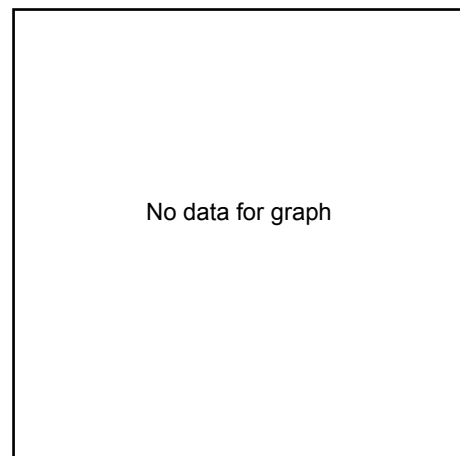
**ADAMTS13 antigen**

**Sample No** 22.51  
**Sample Details** Plasma with an ADAMTS13 activity level <5%  
**Prior Use** Prior Use: None  
**Unit** IU/mL  
**Expiry Date** 31-January-2024  
**Homogeneity** 0.0 % **Homogeneity Parameter** ADAMTS13  
**Number of Participants** 143  
**Number of Responders** 15 **Response Rate** 10 %  
**Comments** The following participant reported a deviating result which was excluded in the statistical evaluation:  
**9055** : 3 IU/mL

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

**Other Reagents**

|                                     | n  | assigned value | Uncert. | CV (%) | Range       |
|-------------------------------------|----|----------------|---------|--------|-------------|
| <b>Enzyme Immuno Assay</b>          | 10 | 0.01           | 0.00    | 59.0   | 0.00 - 0.03 |
| Technozym ADAMTS13 activity/antigen | 2  | 0.02           |         |        | 0.01 - 0.02 |
| Technozym ADAMTS13 antigen          | 8  | 0.01           |         |        | 0.00 - 0.03 |



**ADAMTS13 - I**

**ADAMTS13 antigen**

**Sample No** 22.52  
**Sample Details** Borderline Coagulation Control Plasma  
**Prior Use** Prior Use: None  
**Unit** IU/mL  
**Expiry Date** 31-December-2022  
**Homogeneity** 1.5 %

**Homogeneity Parameter** APTT

For any method used for the measurement of this parameter with a CV ≤ 5.0% 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** 143

**Number of Responders** 15

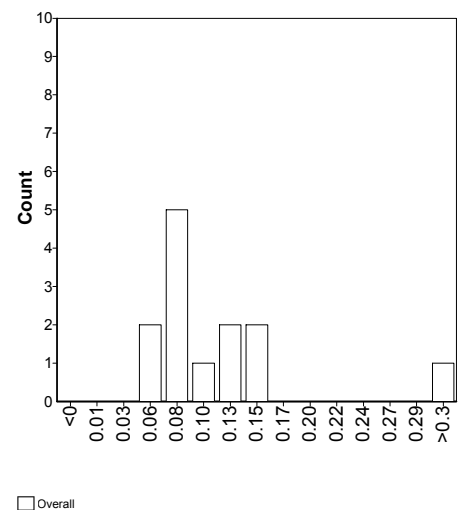
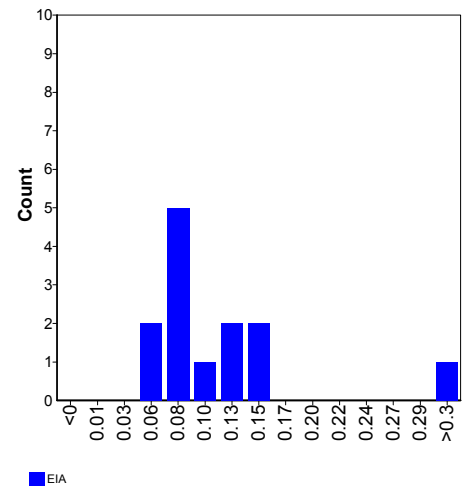
**Response Rate** 10 %

**Comments** The following participant reported a deviating result which was excluded in the statistical evaluation:  
**9055** : 2 IU/mL

| Classification Overview | Normal | BorderLine normal | Borderline abnormal | Abnormal | No classification |
|-------------------------|--------|-------------------|---------------------|----------|-------------------|
| <b>Total</b>            | 1      | 1                 | 1                   | 12       | 0                 |

**Other Reagents**

|                                     | n  | assigned value | Uncert. | CV (%) | Range       |
|-------------------------------------|----|----------------|---------|--------|-------------|
| <b>Enzyme Immuno Assay</b>          | 13 | 0.10           | 0.02    | 43.9   | 0.05 - 0.42 |
| Technozym ADAMTS13 activity/antigen | 4  | 0.08           |         |        | 0.06 - 0.42 |
| Technozym ADAMTS13 antigen          | 9  | 0.10           |         |        | 0.05 - 0.16 |



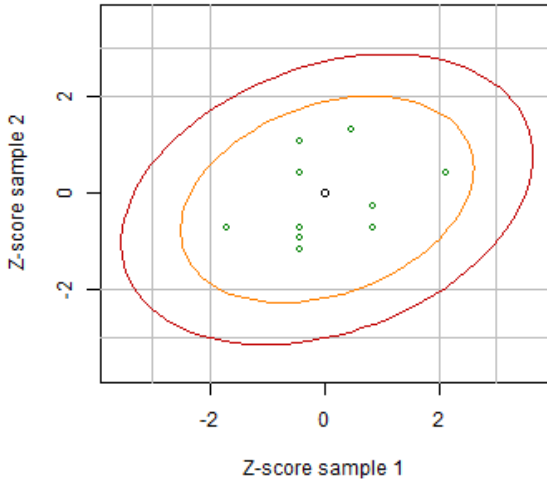
ADAMTS13 - I

ADAMTS13 antigen

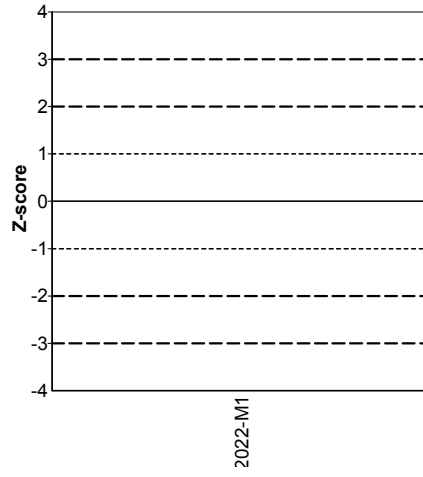
Instrument ID

Bivariate Z-score plots (by survey)

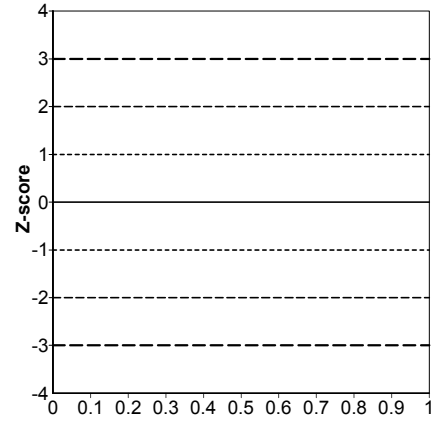
● Needs attention ■ Unsatisfactory ▲ Outlier ○ Your Result



Z-score history (by survey)



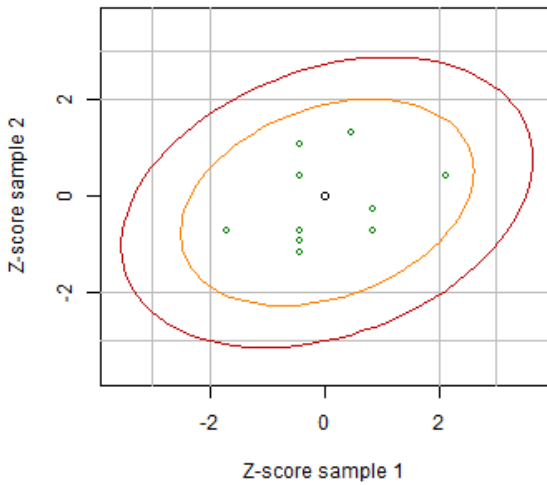
Z-score history (by consensus value)



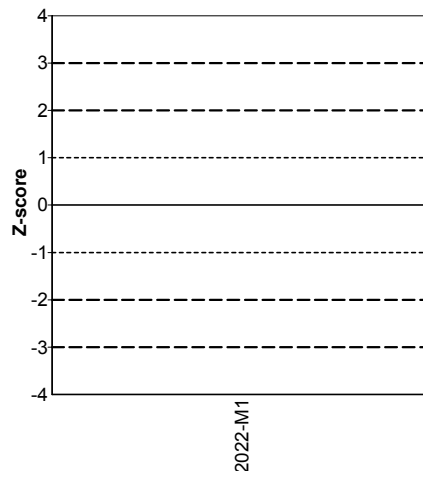
Instrument ID

Bivariate Z-score plots (by survey)

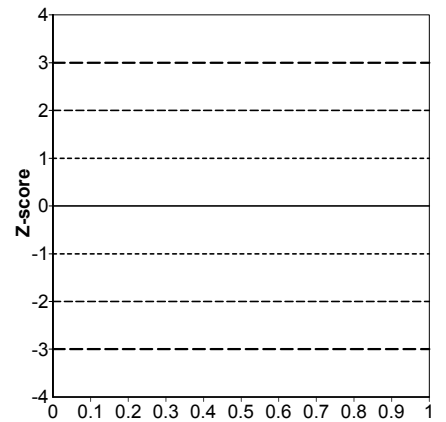
● Needs attention ■ Unsatisfactory ▲ Outlier ○ Your Result



Z-score history (by survey)



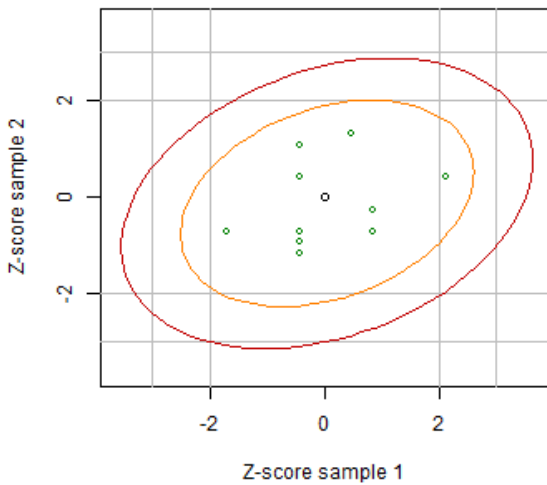
Z-score history (by consensus value)



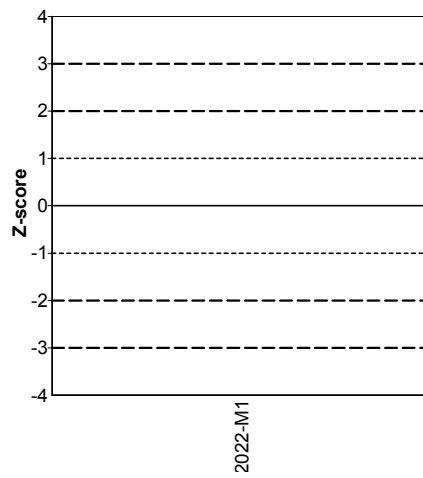
Instrument ID

Bivariate Z-score plots (by survey)

● Needs attention ■ Unsatisfactory ▲ Outlier ○ Your Result



Z-score history (by survey)



Z-score history (by consensus value)

