

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2020-M4

Main

Labcode 99906936

Date of Issue : 16-January-2021

Survey : 2020-M4

Report : Main

Note:

In the Survey Manual 2020 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2020 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.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **March 2nd, 2021**.

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 .

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Appendices are an integral part of the total report.

OVERVIEW Z-SCORES



Satisfactory ($-2 \leq Z\text{-score} \leq 2$)



Need attention ($-3 < Z\text{-score} < -2$ or $2 < Z\text{-score} < 3$)



Unsatisfactory ($Z\text{-score} \leq -3$ or ≥ 3)

| Module | Parameter | Sample | Test System | Total | Assay | Method |
|-----------------------|-----------------------|--------|-------------|-------|-------|--------|
| Factor VIII inhibitor | Factor VIII Inhibitor | 20.187 | 1 | -0.87 | -0.83 | -1.15 |
| | | 20.188 | 1 | -1.24 | -1.12 | -1.26 |

| | |
|------------------------------|------------------------------|
| Factor VIII inhibitor | Factor VIII Inhibitor |
|------------------------------|------------------------------|

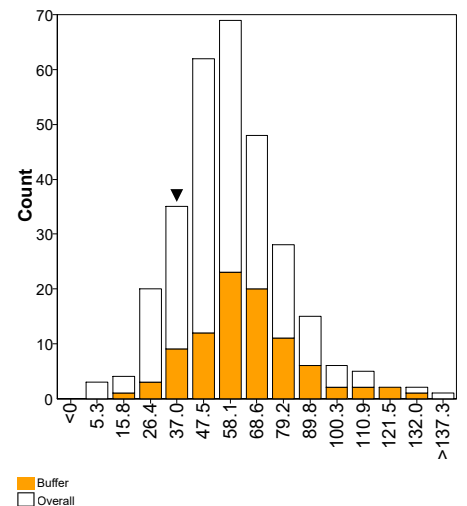
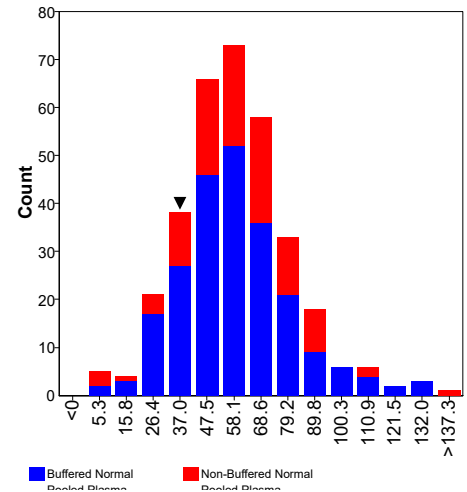
| | | | |
|-------------------------------|---|------------------------------|-----------------|
| Sample No | 20.187 | | |
| Sample Details | Plasma with a Factor VIII Inhibitor level of approx. 55 BU/mL | | |
| Prior Use | Prior Use: None | | |
| Unit | Units: BU/mL | | |
| Expiry Date | 28-February-2023 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | FVIII inhibitor |
| Number of Participants | 357 | | |
| Number of Responders | 322 | Response Rate | 90 % |
| Comments | None. | | |

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|--------------------------------------|-----|----------------|---------|--------|--------------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 334 | 58.1 | 1.35 | 34.0 | 1.7 - 255.0 | 40.8 | -0.87 | | | | |
| Buffered Normal Pooled Plasma | 228 | 57.3 | 1.64 | 34.6 | 1.7 - 133.6 | 40.8 | -0.83 | | | | |
| Buffer | 92 | 62.8 | 2.50 | 30.6 | 17.6 - 128.6 | 40.8 | -1.15 | | | | |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|--|-----|----------------|---------|--------|--------------|
| Total Group | 334 | 58.1 | 1.35 | 34.0 | 1.7 - 255.0 |
| Non-Buffered Normal Pooled Plasma | 106 | 59.8 | 2.35 | 32.4 | 3.0 - 255.0 |
| Buffer | 66 | 59.3 | 2.90 | 31.8 | 6.0 - 115.0 |
| Buffer + Albumin | 2 | 55.0 | | | 40.6 - 69.4 |
| Factor VIII Deficient Plasma | 18 | 57.5 | 6.38 | 37.7 | 16.7 - 255.0 |
| Heat-activated normal plasma | 4 | 52.0 | | | 7.1 - 76.8 |
| Other | 15 | 66.2 | 5.58 | 26.1 | 3.0 - 90.0 |
| Unknown | 1 | 80.0 | | | - |
| Buffered Normal Pooled Plasma | 228 | 57.3 | 1.64 | 34.6 | 1.7 - 133.6 |
| Buffer + Albumin | 19 | 63.4 | 4.29 | 23.6 | 40.0 - 96.0 |
| Factor VIII Deficient Plasma | 85 | 48.5 | 2.21 | 33.6 | 1.7 - 133.6 |
| Heat-inactivated normal plasma | 20 | 57.8 | 6.77 | 41.9 | 20.0 - 100.0 |
| Other | 9 | 65.5 | | | 30.2 - 128.0 |
| Unknown | 3 | 70.0 | | | 64.0 - 83.0 |



| | |
|------------------------------|------------------------------|
| Factor VIII inhibitor | Factor VIII Inhibitor |
|------------------------------|------------------------------|

Sample No 20.188

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 5.5 BU/mL

Prior Use Prior Use: None

Unit Units: BU/mL

Expiry Date 28-February-2023

Homogeneity 5.1 % **Homogeneity Parameter** FVIII inhibitor

For any method used for the measurement of this parameter with a CV ≤ 17.0% 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 357

Number of Responders 322 **Response Rate** 90 %

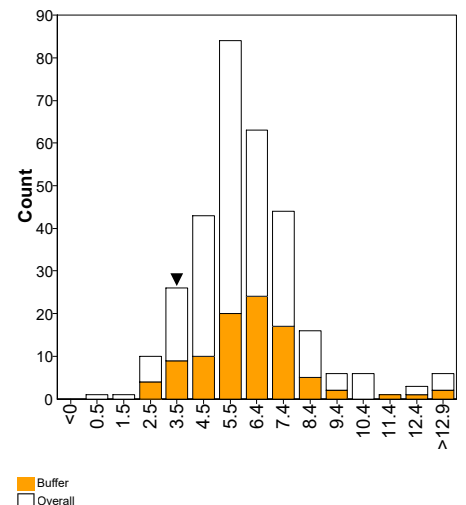
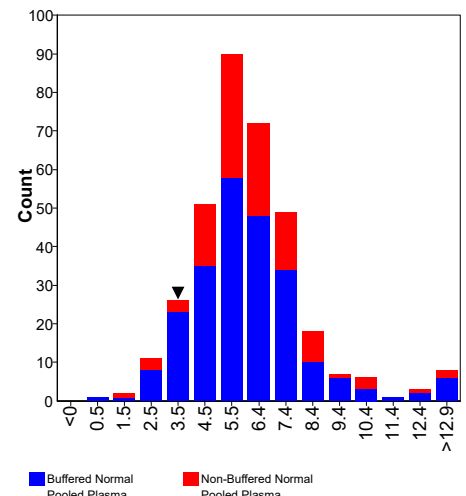
Comments None.

Own Reagent

| | n | assigned value | Uncert. | CV (%) | Range | your result | z-score | your result | z-score | your result | z-score |
|-------------------------------|-----|----------------|---------|--------|------------|-------------|---------|-------------|---------|-------------|---------|
| Total Group | 345 | 5.9 | 0.11 | 28.6 | 0.7 - 38.8 | 3.8 | -1.24 | | | | |
| Buffered Normal Pooled Plasma | 236 | 5.8 | 0.14 | 30.7 | 0.7 - 38.8 | 3.8 | -1.12 | | | | |
| Buffer | 95 | 6.0 | 0.22 | 28.9 | 2.5 - 38.8 | 3.8 | -1.26 | | | | |

Other Reagents

| | n | assigned value | Uncert. | CV (%) | Range |
|-----------------------------------|-----|----------------|---------|--------|------------|
| Total Group | 345 | 5.9 | 0.11 | 28.6 | 0.7 - 38.8 |
| Non-Buffered Normal Pooled Plasma | 109 | 6.1 | 0.17 | 24.0 | 1.7 - 17.0 |
| Buffer | 68 | 6.1 | 0.22 | 24.4 | 2.4 - 12.0 |
| Buffer + Albumin | 2 | 6.0 | | | 5.7 - 6.3 |
| Factor VIII Deficient Plasma | 18 | 6.2 | 0.50 | 27.2 | 2.8 - 14.0 |
| Heat-activated normal plasma | 4 | 6.2 | | | 4.4 - 8.4 |
| Other | 16 | 5.9 | 0.38 | 20.5 | 1.7 - 17.0 |
| Unknown | 1 | 6.0 | | | - |
| Buffered Normal Pooled Plasma | 236 | 5.8 | 0.14 | 30.7 | 0.7 - 38.8 |
| Buffer + Albumin | 19 | 6.0 | 0.19 | 10.8 | 3.7 - 8.0 |
| Factor VIII Deficient Plasma | 90 | 5.4 | 0.22 | 30.7 | 0.7 - 18.0 |
| Heat-inactivated normal plasma | 20 | 6.0 | 0.57 | 34.0 | 2.6 - 10.5 |
| Other | 9 | 5.8 | | | 2.8 - 32.0 |
| Unknown | 3 | 6.5 | | | 5.5 - 9.1 |

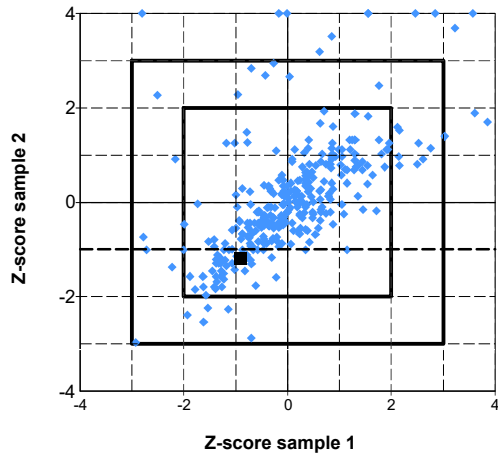


Factor VIII inhibitor

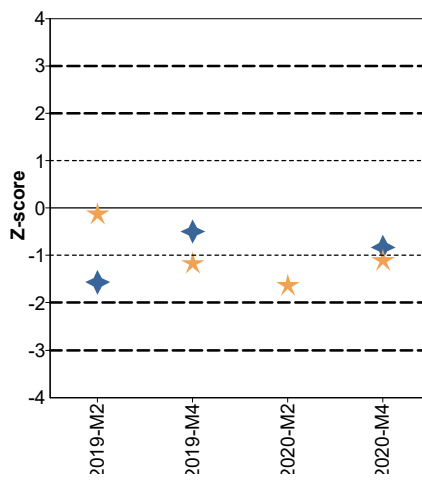
Factor VIII Inhibitor

Instrument ID

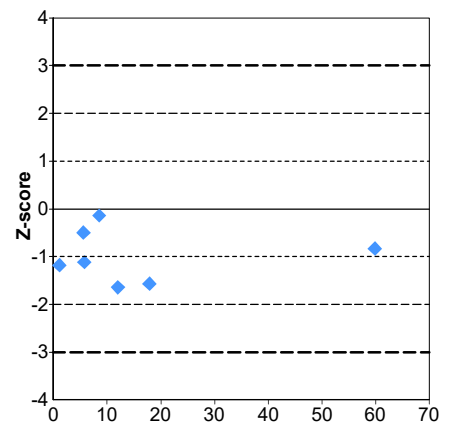
Z-score plot



Z-score history (by survey)

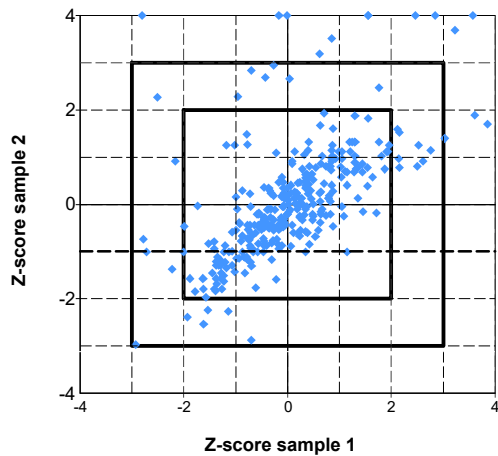


Z-score history (by consensus value)

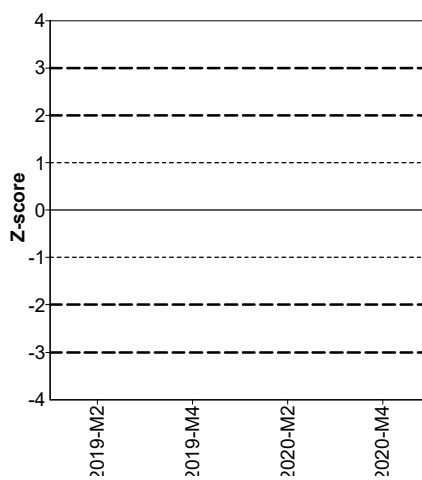


Instrument ID

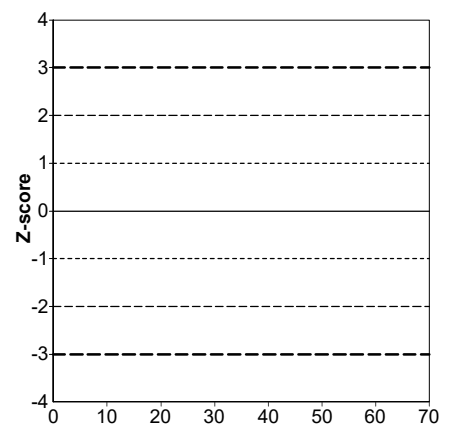
Z-score plot



Z-score history (by survey)

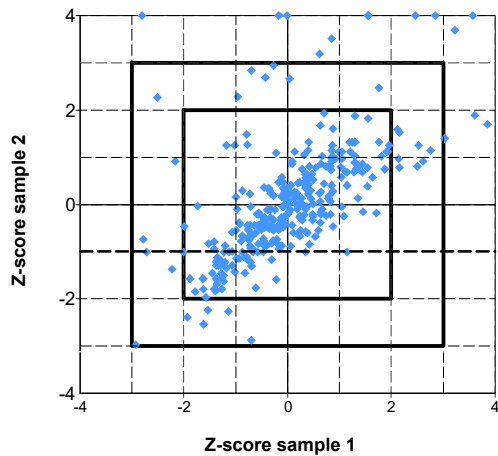


Z-score history (by consensus value)

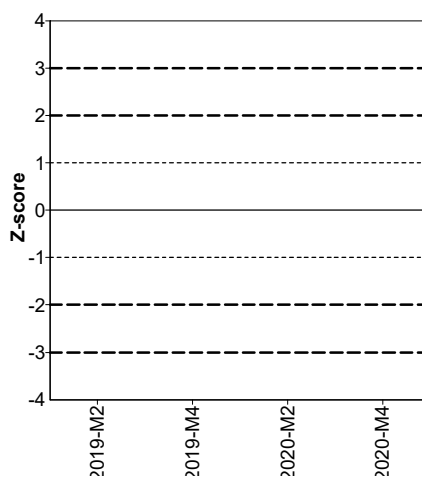


Instrument ID

Z-score plot



Z-score history (by survey)



Z-score history (by consensus value)

