

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-H1

Haemophilia

Labcode 1492

Date of Issue : 08-May-2023

Survey : 2023-H1

Report : Haemophilia

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.

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.

Multiple instruments

Participants have the possibility to submit per parameter results for three different instruments and or methods. However, some participants (**labcodes 3816 and 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. The results from the second and third test system have been excluded in the statistical analysis.

Please, do not submit multiple times the same results anymore in future surveys.

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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Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
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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: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor IX Inhibitor	Factor IX Inhibitor	23.61	1	0.17	0.21	0.19	
		23.62	1	1.46	1.57	1.48	

Factor IX Inhibitor	Factor IX Inhibitor
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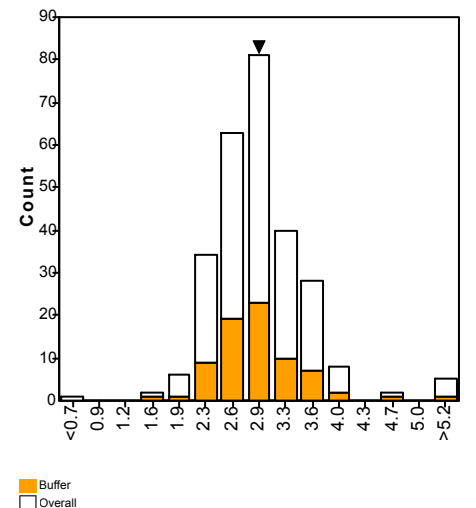
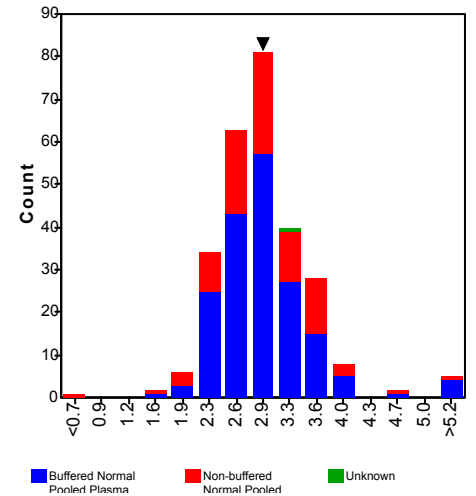
Sample No	23.61		
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 2.5 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-December-2025		
Homogeneity	2.8 %	Homogeneity Parameter	FIX inhibitor
For any method used for the measurement of this parameter with a CV ≤ 9.3% the criterion for 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	266		
Number of Responders	256	Response Rate	96 %
Comments	None		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	270	2.9	0.04	17.2	0.3 - 11.0	3.0	0.17				
Buffered Normal Pooled Plasma	181	2.9	0.04	16.5	1.6 - 11.0	3.0	0.21				
Buffer	74	2.9	0.07	15.7	1.6 - 5.3	3.0	0.19				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	270	2.9	0.04	17.2	0.3 - 11.0
Unknown	1	3.2			-
Factor IX deficient plasma	1	3.2			-
Buffered Normal Pooled Plasma	181	2.9	0.04	16.5	1.6 - 11.0
Buffer + Albumin	19	2.9	0.14	16.8	2.2 - 3.7
Factor IX deficient plasma	69	2.9	0.07	16.9	1.9 - 11.0
Heat-inactivated normal plasma	7	2.6			2.0 - 3.3
Other	10	3.2	0.32	25.3	2.2 - 10.4
Unknown	2	2.6			2.5 - 2.7
Non-buffered Normal Pooled Plasma	88	2.9	0.07	19.0	0.3 - 7.9
Buffer	47	2.9	0.10	19.4	0.3 - 7.9
Buffer + Albumin	5	3.2			2.5 - 3.5
Factor IX deficient plasma	22	2.9	0.15	20.1	1.7 - 4.0
Heat-inactivated normal plasma	3	4.0			3.0 - 4.8
Other	10	3.0	0.24	20.2	2.4 - 4.0
Unknown	1	3.0			-



Factor IX Inhibitor	Factor IX Inhibitor
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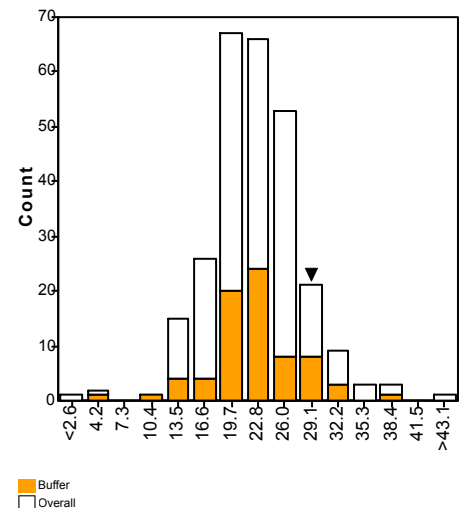
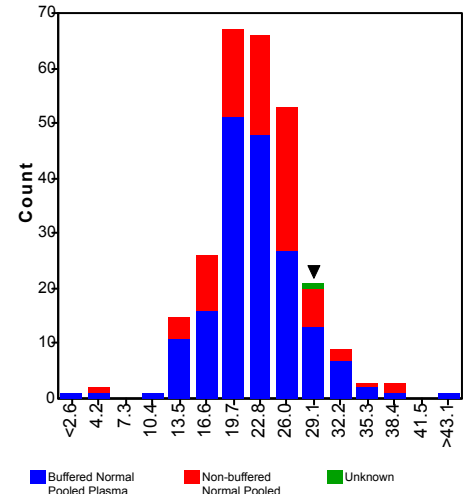
Sample No	23.62		
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 20 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-December-2025		
Homogeneity	0.0 %	Homogeneity Parameter	FIX inhibitor
Number of Participants	266	Response Rate	96 %
Number of Responders	256		
Comments	None		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	268	22.4	0.37	21.7	2.0 - 51.0	29.5	1.46				
Buffered Normal Pooled Plasma	180	22.2	0.44	21.1	2.0 - 51.0	29.5	1.57				
Buffer	74	22.5	0.69	21.0	5.7 - 37.0	29.5	1.48				

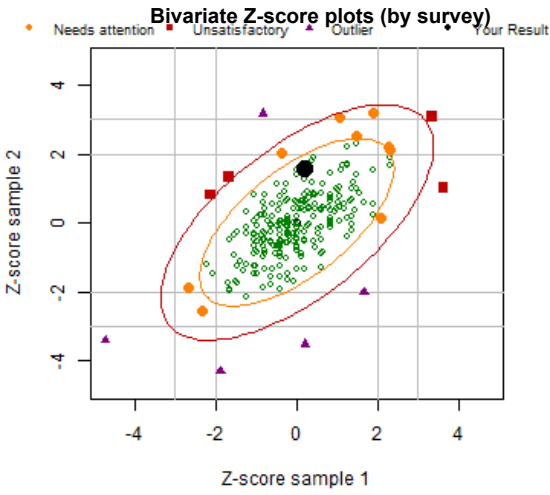
Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	268	22.4	0.37	21.7	2.0 - 51.0
Unknown	1	30.0			-
Factor IX deficient plasma	1	30.0			-
Buffered Normal Pooled Plasma	180	22.2	0.44	21.1	2.0 - 51.0
Buffer + Albumin	19	21.8	1.29	20.6	12.8 - 33.0
Factor IX deficient plasma	68	22.3	0.67	19.9	13.0 - 36.5
Heat-inactivated normal plasma	7	14.9			2.0 - 23.0
Other	10	24.8	2.34	23.9	19.6 - 51.0
Unknown	2	18.3			17.6 - 19.0
Non-buffered Normal Pooled Plasma	87	22.9	0.68	22.1	5.6 - 39.0
Buffer	47	22.4	0.84	20.4	5.6 - 34.1
Buffer + Albumin	5	26.1			18.5 - 28.8
Factor IX deficient plasma	21	22.6	1.92	31.1	14.0 - 39.0
Heat-inactivated normal plasma	3	25.0			24.0 - 38.4
Other	10	23.2	1.26	13.7	15.5 - 26.4
Unknown	1	22.0			-

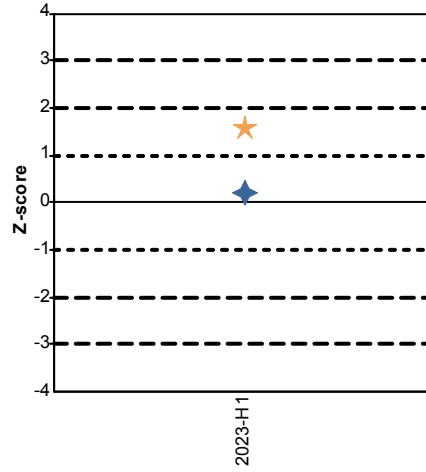


Factor IX Inhibitor

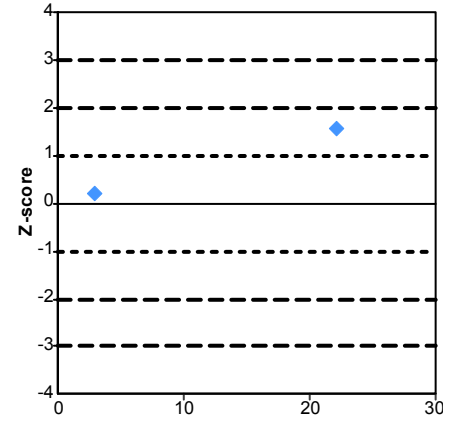
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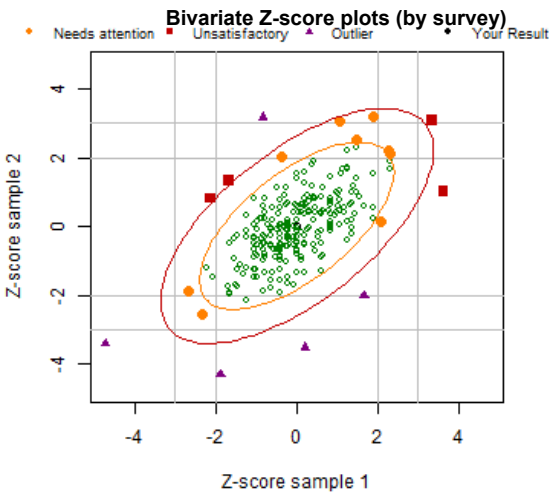
Z-score history (by survey)



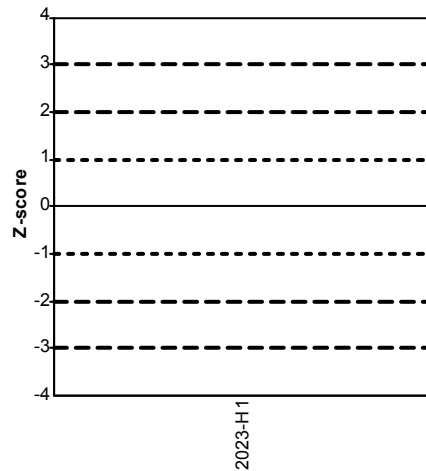
Z-score history (by consensus value)



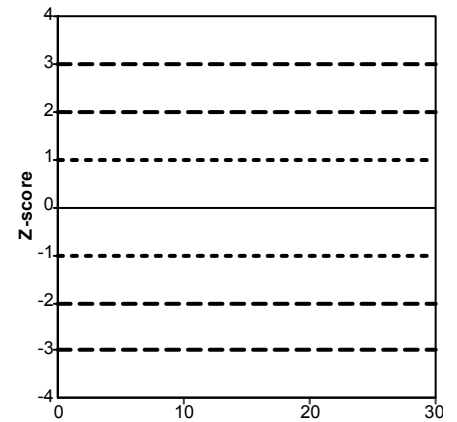
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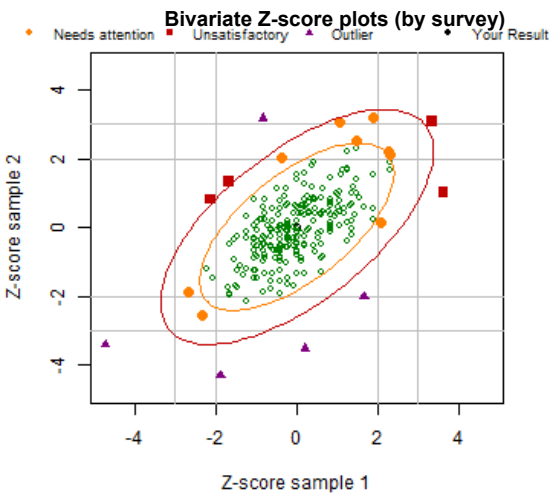
Z-score history (by survey)



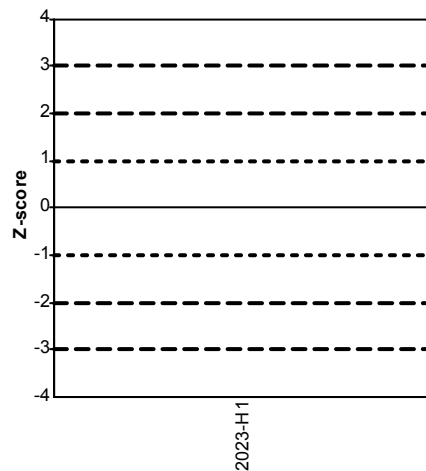
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

