

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-H1

Haemophilia

Labcode 1492

Date of Issue : 22-April-2025

Survey : 2025-H1

Report : Haemophilia

Note:

In the Survey Manual 2025 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2025 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

Exclusion of results

Results < [value] or > [value] are excluded from the statistical analysis. When other results (e.g. deviating results) are excluded from the statistical analysis, these results are placed between brackets.

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 from the statistical analysis. Do not submit multiple times the same results anymore in future surveys.

Kovaltry and Jivi

Because of the limited number of results for both parameters: Kovaltry (Clotting/Chromogenic) and Jivi (Clotting/Chromogenic), the minimum number used for the calculation of the CV and Z-score is 5.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **June 24th, 2025**. Complaints received after this date will not be taken into consideration.

This report is authorized by: Dr.P.Meijer (Director)

Note: The current Survey Manual can be downloaded from the 'Participant Area' of the ECAT website. Login and select the option 'View Documents'.

ECAT Foundation

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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	25.61	1	0.76	0.72	0.73	
		25.62	1	1.05	1.02	1.18	

Factor IX Inhibitor

Sample No 25.61
Sample Details Plasma with a Factor IX Inhibitor level of approx. 2.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-October-2027
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 267
Number of Responders 253 **Response Rate** 95 %

Comments Participants **3816** and **3828** have submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

The following participants reported deviating results which were excluded from the statistical analysis:

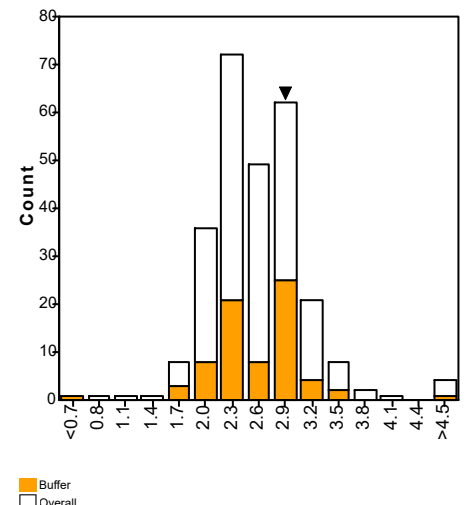
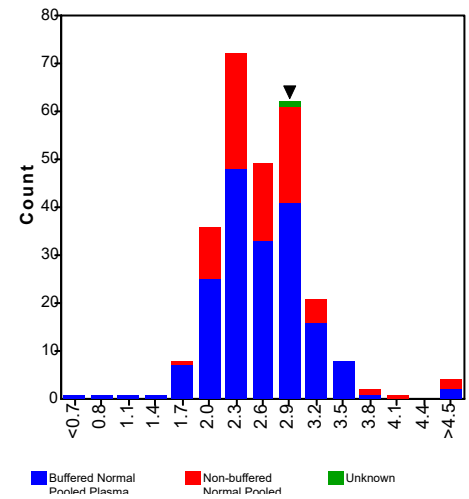
203: 54.50 BU/mL
3855: 0 BU/mL

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	267	2.6	0.03	17.5	0.7 - 8.8	2.9	0.76				
Buffered Normal Pooled Plasma	185	2.6	0.04	18.5	0.7 - 8.8	2.9	0.72				
Buffer	73	2.6	0.07	17.9	0.7 - 4.5	2.9	0.73				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	267	2.6	0.03	17.5	0.7 - 8.8
Unknown	1	2.9			-
Buffer	1	2.9			-
Buffered Normal Pooled Plasma	185	2.6	0.04	18.5	0.7 - 8.8
Buffer + Albumin	17	2.4	0.11	15.4	1.9 - 3.2
Factor IX deficient plasma	77	2.6	0.07	18.2	0.7 - 3.8
Heat-inactivated normal plasma	8	2.4			1.4 - 3.4
Other	9	2.7			2.0 - 8.8
Unknown	1	1.7			-
Non-buffered Normal Pooled Plasma	81	2.6	0.06	15.8	1.9 - 6.0
Buffer	42	2.6	0.07	15.0	2.0 - 5.5
Buffer + Albumin	2	3.0			3.0 - 3.1
Factor IX deficient plasma	25	2.5	0.08	13.3	2.0 - 3.9
Heat-inactivated normal plasma	3	2.9			2.9 - 6.0
Other	8	2.2			1.9 - 3.1
Unknown	1	2.0			-



Factor IX Inhibitor

Sample No 25.62
Sample Details Plasma with a Factor IX Inhibitor level of approx. 7.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-October-2027
Homogeneity 3.8 % **Homogeneity Parameter** FIX inhibitor
 For any method used for the measurement of this parameter with a CV ≤ 12.7% 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 267
Number of Responders 253 **Response Rate** 95 %

Comments Participants **3816** and **3828** have submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

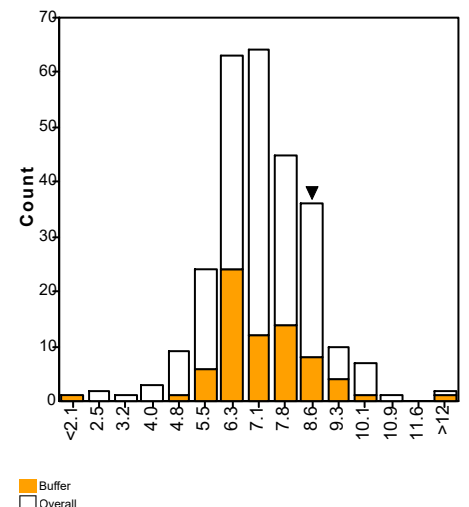
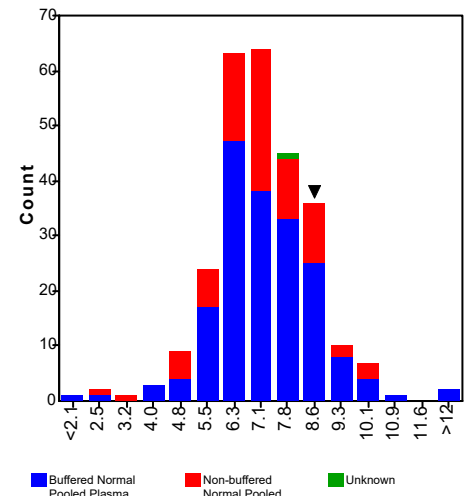
The following participant reported a deviating result which was excluded from the statistical analysis:
3855: 0 BU/mL

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	268	7.1	0.09	17.1	1.7 - 14.6	8.4	1.05				
Buffered Normal Pooled Plasma	184	7.2	0.11	17.0	1.7 - 14.6	8.4	1.02				
Buffer	72	7.1	0.16	15.7	1.7 - 14.5	8.4	1.18				

Other Reagents

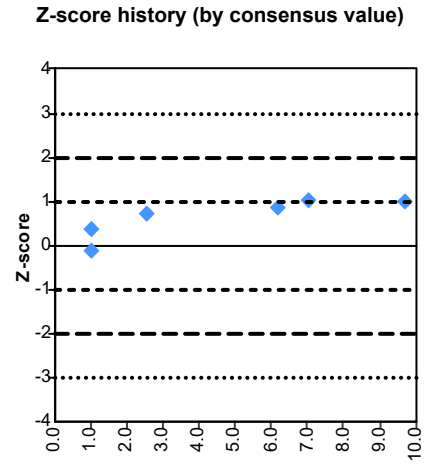
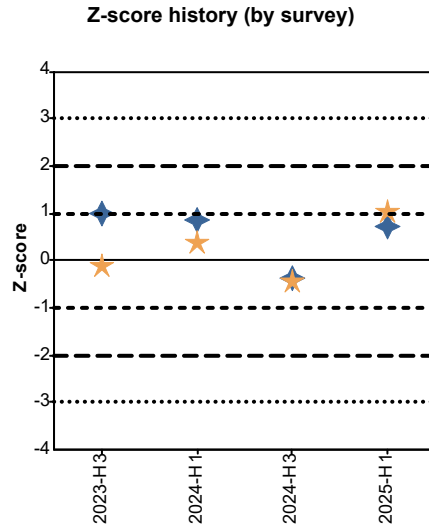
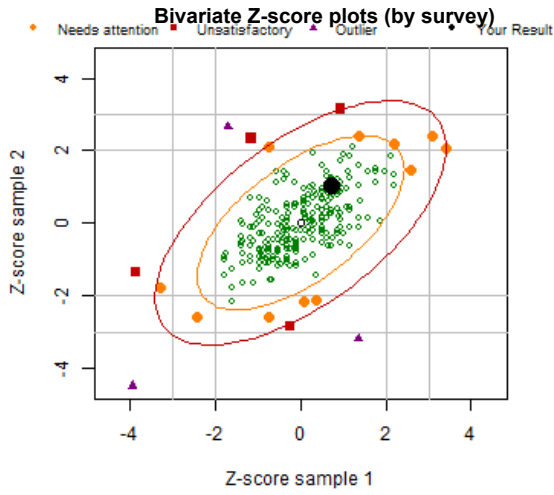
	n	assigned value	Uncert.	CV (%)	Range
Total Group	268	7.1	0.09	17.1	1.7 - 14.6
Unknown	1	8.0			-
Buffer	1	8.0			-
Buffered Normal Pooled Plasma	184	7.2	0.11	17.0	1.7 - 14.6
Buffer + Albumin	17	7.3	0.37	16.6	3.7 - 14.6
Factor IX deficient plasma	77	7.2	0.18	17.5	4.0 - 11.0
Heat-inactivated normal plasma	8	6.5			4.0 - 8.5
Other	9	7.0			2.4 - 9.8
Unknown	1	5.4			-
Non-buffered Normal Pooled Plasma	83	7.0	0.17	17.5	2.3 - 10.4
Buffer	42	6.9	0.22	16.8	4.4 - 10.4
Buffer + Albumin	2	8.6			7.8 - 9.4
Factor IX deficient plasma	26	7.3	0.29	16.2	5.1 - 9.6
Heat-inactivated normal plasma	3	7.5			7.2 - 8.3
Other	9	6.7			2.3 - 8.8
Unknown	1	5.0			-



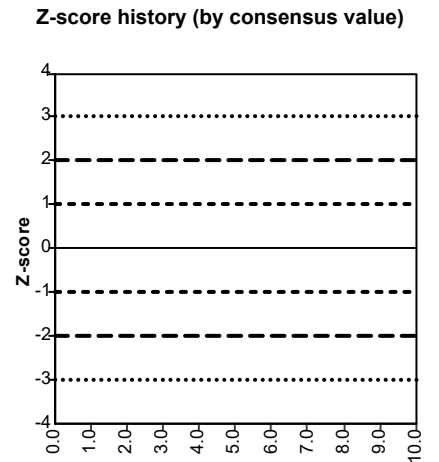
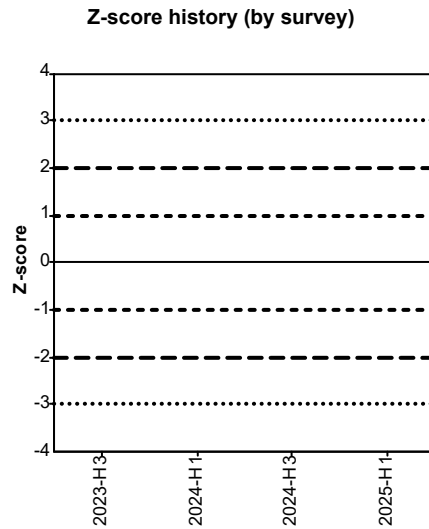
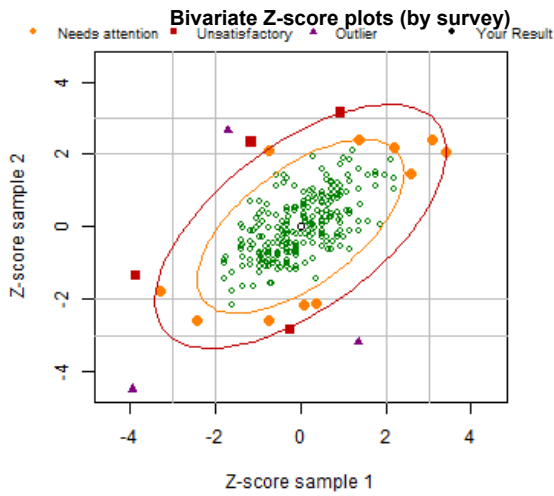
Factor IX Inhibitor

Factor IX Inhibitor

Instrument ID



Instrument ID



Instrument ID

