

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-H3

Haemophilia

Labcode 1492

Date of Issue : 20-October-2025

Survey : 2025-H3

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 **December 16th, 2025**.

Complaints received after this date will not be taken into consideration.

This report is authorized by: 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 ($-2 \leq \text{Z-score} \leq 2$)
  UV: Need attention ($-3 < \text{Z-score} < -2$ or $2 < \text{Z-score} < 3$)
  UV:Unsatisfactory ($\text{Z-score} \leq -3$ or ≥ 3)
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor IX Inhibitor	Factor IX Inhibitor	25.180	1	 1.51	 1.50	 1.51	
		25.181	1	 0.61	 0.57	 0.64	

Factor IX Inhibitor

Sample No	25.180		
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 13 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-April-2028		
Homogeneity	0.0 %	Homogeneity Parameter	FIX inhibitor
Number of Participants	274		
Number of Responders	260	Response Rate	95 %
Comments	Participants 518B and 1480 reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25.180 and 25.181.		

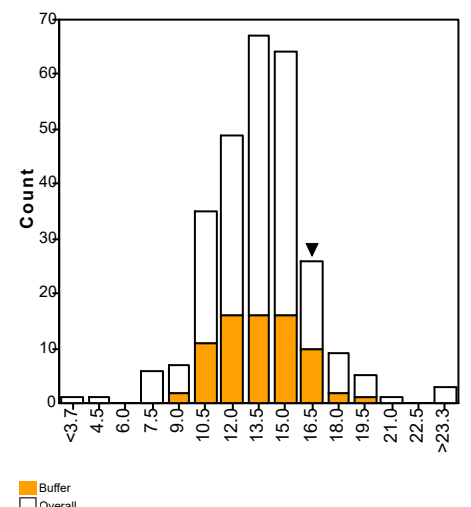
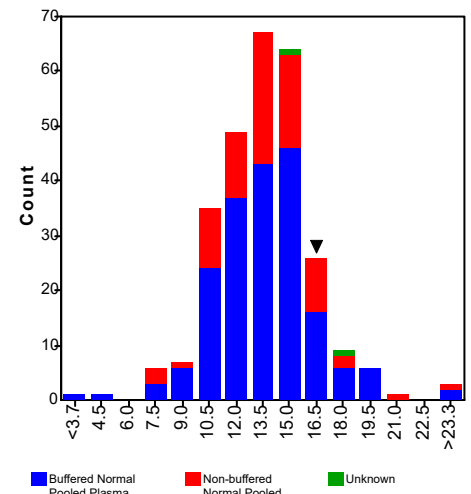
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	275	13.5	0.18	17.8	2.5 - 26.9	17.2	1.51				
Buffered Normal Pooled Plasma	191	13.5	0.22	18.2	2.5 - 26.9	17.2	1.50				
Buffer	74	13.6	0.35	17.8	8.7 - 20.0	17.2	1.51				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	275	13.5	0.18	17.8	2.5 - 26.9
Unknown	2	16.6			15.2 - 18.0
Buffer	1	15.2			-
Factor IX deficient plasma	1	18.0			-
Buffered Normal Pooled Plasma	191	13.5	0.22	18.2	2.5 - 26.9
Buffer + Albumin	18	13.4	0.64	16.2	8.0 - 16.5
Factor IX deficient plasma	78	13.7	0.35	17.8	4.0 - 26.9
Heat-inactivated normal plasma	7	11.0			2.5 - 12.6
Other	13	13.9	1.58	32.9	7.5 - 20.2
Non-buffered Normal Pooled Plasma	82	13.6	0.31	16.8	7.2 - 25.6
Buffer	41	13.3	0.40	15.5	8.0 - 18.0
Buffer + Albumin	2	15.5			14.8 - 16.2
Factor IX deficient plasma	27	13.6	0.61	18.5	7.2 - 25.6
Heat-inactivated normal plasma	3	17.2			10.0 - 20.8
Other	8	14.1			10.5 - 16.1
Unknown	1	13.6			-



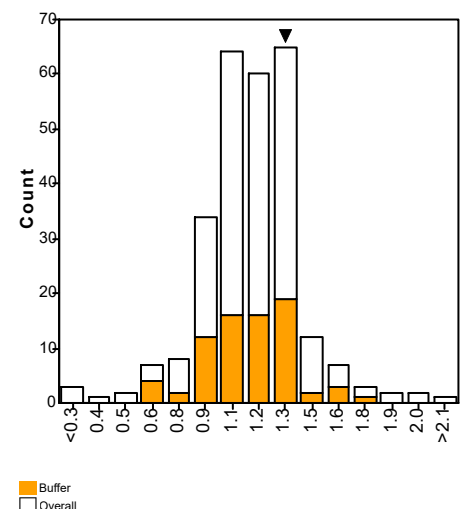
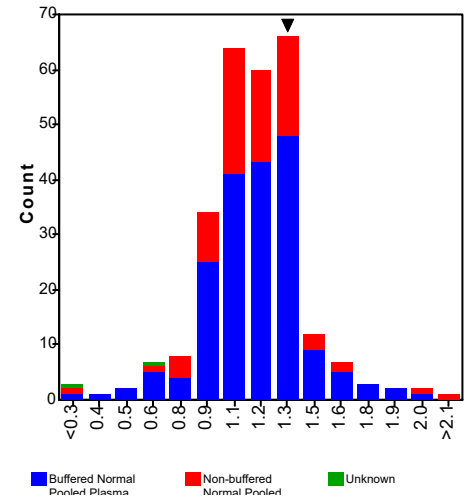
Factor IX Inhibitor		Factor IX Inhibitor	
Sample No	25.181		
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 1 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-April-2028		
Homogeneity	3.0 %	Homogeneity Parameter	FIX inhibitor
	For any method used for the measurement of this parameter with a $CV \leq 10.0\%$ 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	274		
Number of Responders	260	Response Rate	95 %
Comments	Participants 518B and 1480 reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25.180 and 25.181.		
	Participant 3828 has 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.		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	272	1.2	0.02	19.2	0.0 - 2.2	1.3	0.61				
Buffered Normal Pooled Plasma	190	1.2	0.02	19.2	0.0 - 2.0	1.3	0.57				
Buffer	75	1.1	0.03	20.5	0.6 - 1.7	1.3	0.64				

Other Reagents

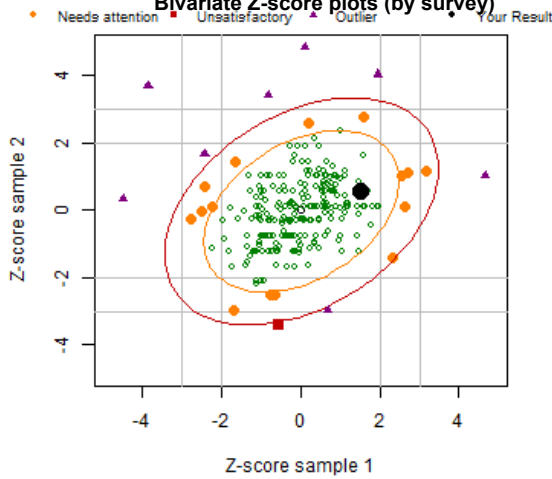
	n	assigned value	Uncert.	CV (%)	Range
Total Group	272	1.2	0.02	19.2	0.0 - 2.2
Unknown	2	0.3			0.0 - 0.6
Buffer	1	0.6			-
Factor IX deficient plasma	1	0.0			-
Buffered Normal Pooled Plasma	190	1.2	0.02	19.2	0.0 - 2.0
Buffer + Albumin	18	1.2	0.07	19.1	0.4 - 1.9
Factor IX deficient plasma	75	1.2	0.03	17.6	0.0 - 2.0
Heat-inactivated normal plasma	8	1.2			0.9 - 1.9
Other	13	1.2	0.10	24.0	0.9 - 1.6
Non-buffered Normal Pooled Plasma	80	1.2	0.03	18.1	0.0 - 2.2
Buffer	40	1.2	0.05	19.9	0.7 - 2.2
Buffer + Albumin	2	1.2			1.1 - 1.3
Factor IX deficient plasma	27	1.2	0.04	13.0	0.8 - 1.4
Heat-inactivated normal plasma	3	1.4			1.1 - 1.5
Other	7	1.0			0.0 - 1.6
Unknown	1	1.1			-



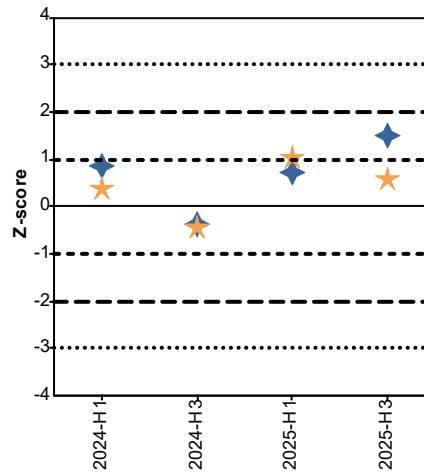
Factor IX Inhibitor

Instrument ID

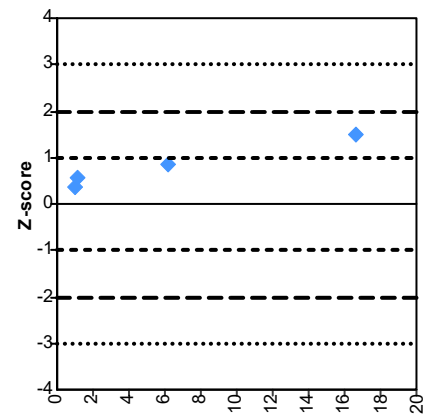
Bivariate Z-score plots (by survey)



Z-score history (by survey)

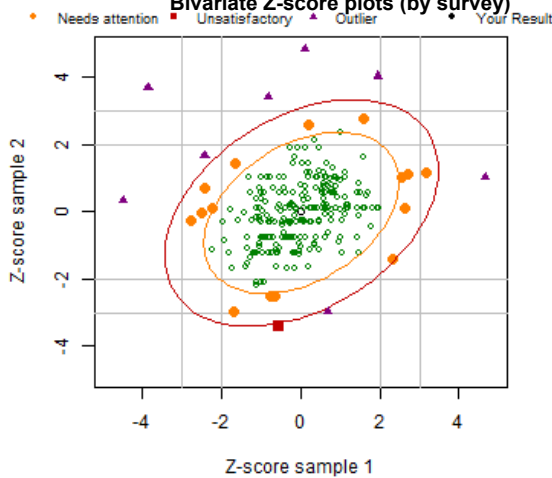


Z-score history (by consensus value)

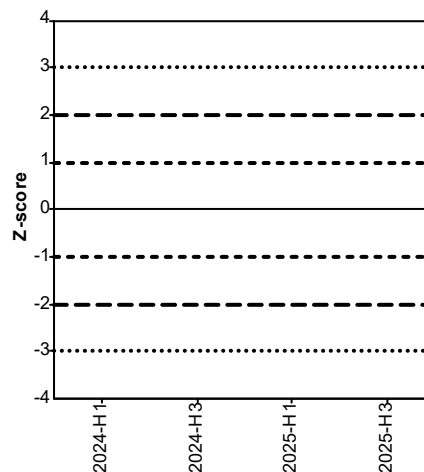


Instrument ID

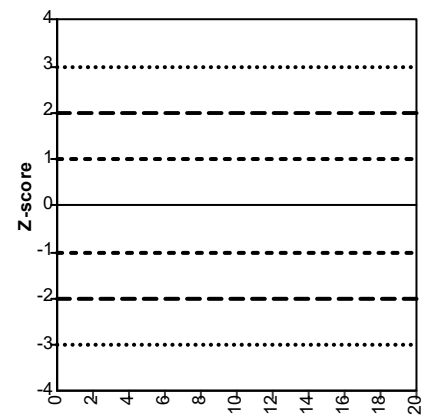
Bivariate Z-score plots (by survey)



Z-score history (by survey)

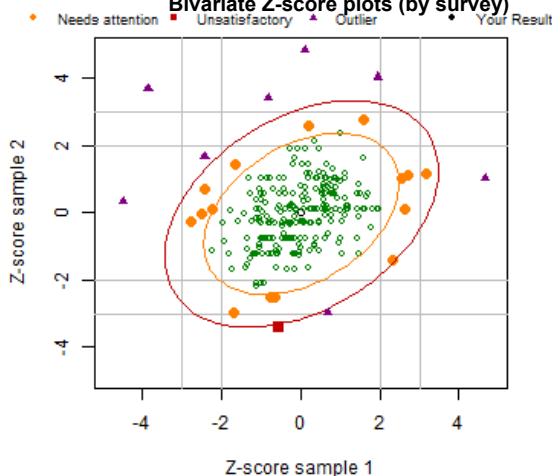


Z-score history (by consensus value)

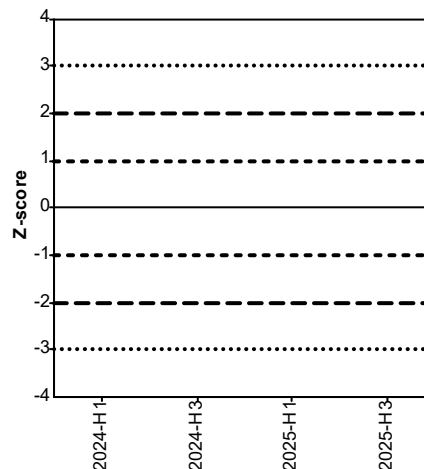


Instrument ID

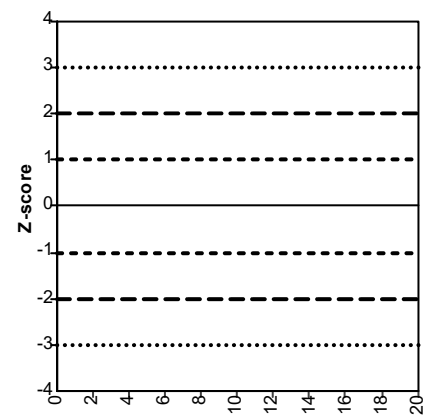
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



FO QK externe, Bewertung von Ringversuchen ohne Zertifikatausgabe

Ringversuch

ECAT	Analyt	Analyt	
	M – Main Programm	ADAMTS13	☐
	L - Lupus Programm	L - Lupus Programm	☐
	H - Hämophilie Programm	F.VIII Inhibitor	☐
2025-H3	H - Hämophilie Programm	F.IX Inhibitor	☒
	P – PFA Programm	PFA-100	☐
Sonstige (frei eintragen)			☐
Sonstige (frei eintragen)			☐

Bewertung (Die Auswertung erfolgt nur durch die fachliche Bereichsleitung)

Die Bewertung der beiden RV-Proben ist zufriedenstellend.
Die Ergebnisse liegen im Kollektivvergleich bei kleine 2 z-score. Probe 25.180 liegt mit 17,2 BE (Soll-13 BE) leicht im oberen Bereich des Kollektiv. Probe 25.181 liegt mit 1,3 BE (Soll-1 BE) sehr gut im Vergleich.
Der Ringversuch wird als bestanden bewertet.

Ringversuchsziel erreicht	ja	nein
2025-H3	☒	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Maßnahme erforderlich	ja	nein
	☐	☒
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Werwitzke
Name

22/10/2025
Datum

S. Werwitzke
Unterschrift