

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-H3

Haemophilia

Labcode 1492

Date of Issue : 28-October-2024

Survey : 2024-H3

Report : Haemophilia

Note:

In the Survey Manual 2024 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2024 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 **December 12th, 2024**.

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

Exclusion of results

Results < [value] or > [value] are excluded in the statistical evaluation.

When other results (e.g. deviating results) are excluded in the statistical evaluation, 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 have submitted three times the same results, suggesting that this are separate results. This is not the case and may affect the statistical evaluation. The results from the second and third test system have been excluded in the statistical evaluation.

Please, 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.

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

Note: The actual Survey Manual can be downloaded by going to the "Participant Area" of the ECAT website, login and go to the option "View Documents".

ECAT Foundation

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General terms of delivery are applicable to all our services.

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	24.176	1	-0.45	-0.37	-0.43	
		24.177	1	-0.55	-0.45	-0.45	

Factor IX Inhibitor

Sample No 24.176
Sample Details Plasma with a Factor IX Inhibitor level of approx. 3.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-April-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 268
Number of Responders 254 **Response Rate** 95 %

Comments The following participant reported a deviating result which was excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the sample 24.176 and 24.177:
9907169: 15.7 BU/mL

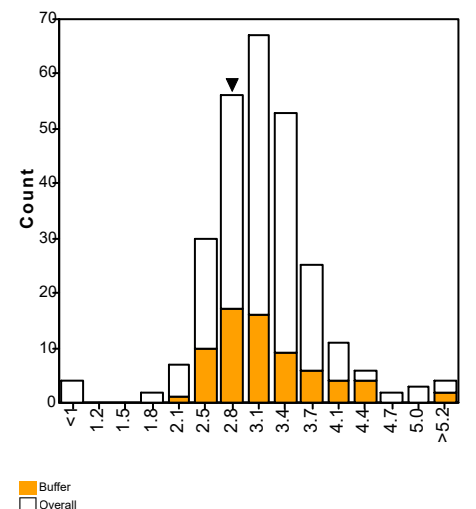
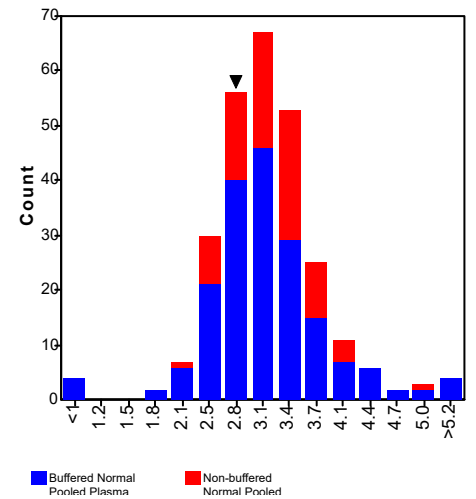
Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical evaluation.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	270	3.1	0.04	16.0	0.2 - 6.7	2.9	-0.45				
Buffered Normal Pooled Plasma	184	3.1	0.05	17.1	0.2 - 6.7	2.9	-0.37				
Buffer	69	3.1	0.08	16.9	2.2 - 6.7	2.9	-0.43				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	270	3.1	0.04	16.0	0.2 - 6.7
Buffered Normal Pooled Plasma	184	3.1	0.05	17.1	0.2 - 6.7
Buffer + Albumin	19	3.0	0.09	10.7	2.0 - 3.4
Factor IX deficient plasma	79	3.1	0.08	17.8	0.3 - 5.5
Heat-inactivated normal plasma	8	3.0			1.7 - 4.7
Other	8	4.0			2.8 - 6.7
Unknown	1	0.2			-
Non-buffered Normal Pooled Plasma	86	3.2	0.06	13.9	2.0 - 5.0
Buffer	44	3.1	0.09	14.6	2.3 - 4.0
Buffer + Albumin	1	3.8			-
Factor IX deficient plasma	26	3.1	0.08	10.2	2.6 - 3.7
Heat-inactivated normal plasma	4	3.4			3.3 - 5.0
Other	10	3.3	0.27	20.5	2.6 - 4.2
Unknown	1	2.0			-



Factor IX Inhibitor	Factor IX Inhibitor
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Sample No 24.177
Sample Details Plasma with a Factor IX Inhibitor level of approx. 13 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-April-2027
Homogeneity 3.1 % **Homogeneity Parameter** FIX inhibitor
 For any method used for the measurement of this parameter with a **CV ≤ 10.3%** 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 268
Number of Responders 254 **Response Rate** 95 %

Comments The following participant reported a deviating result which was excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the sample 24.176 and 24.177:
9907169: 3.9 BU/mL

The following participants reported deviating results which were excluded in the statistical evaluation:
137: 0.0 BU/mL
1226: 1 BU/mL
9907210: 0 BU/mL

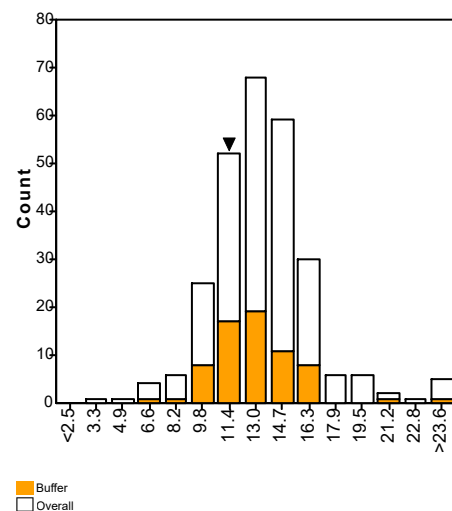
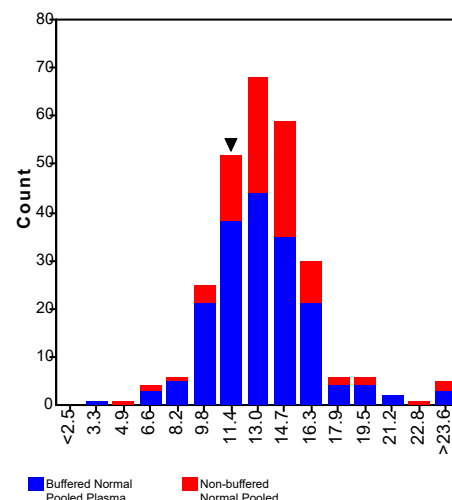
Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical evaluation.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Total Group	266	13.3	0.19	19.0	4.1 - 28.6	11.9	-0.55				
Buffered Normal Pooled Plasma	181	13.1	0.24	20.1	4.1 - 28.6	11.9	-0.45				
Buffer	67	12.9	0.34	17.4	5.8 - 23.8	11.9	-0.45				

Other Reagents

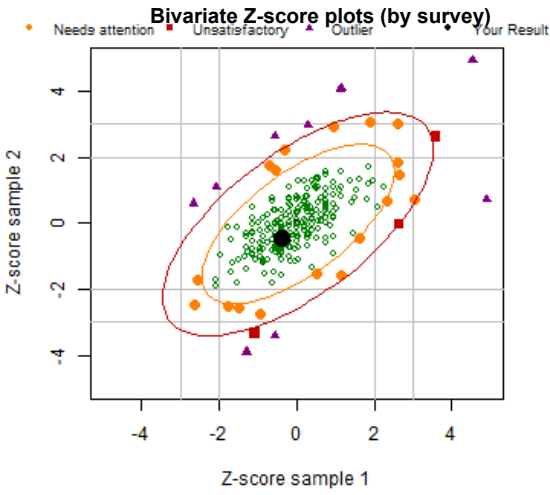
	n	assigned value	Uncert.	CV (%)	Range
Total Group	266	13.3	0.19	19.0	4.1 - 28.6
Buffered Normal Pooled Plasma	181	13.1	0.24	20.1	4.1 - 28.6
Buffer + Albumin	19	13.1	0.65	17.2	8.6 - 16.0
Factor IX deficient plasma	79	13.2	0.40	21.8	6.3 - 26.1
Heat-inactivated normal plasma	7	12.9			6.6 - 16.3
Other	8	15.8			4.1 - 28.6
Unknown	1	7.7			-
Non-buffered Normal Pooled Plasma	85	13.7	0.30	16.4	4.9 - 27.2
Buffer	44	13.7	0.48	18.7	4.9 - 25.7
Buffer + Albumin	1	15.4			-
Factor IX deficient plasma	26	13.2	0.44	13.6	6.2 - 22.9
Heat-inactivated normal plasma	4	14.9			14.0 - 27.2
Other	9	13.0			11.2 - 20.3
Unknown	1	15.0			-



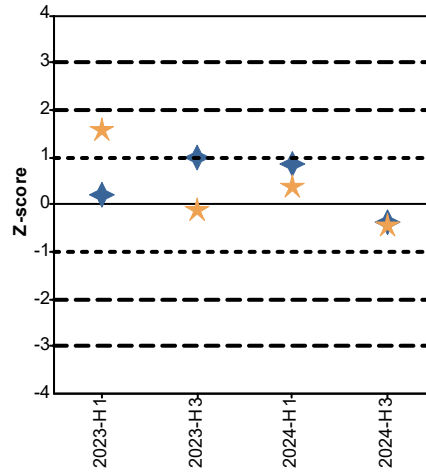
Factor IX Inhibitor

Factor IX Inhibitor

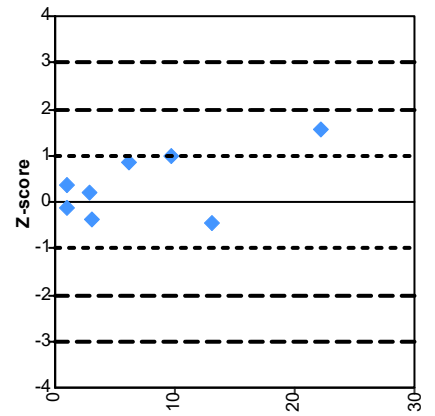
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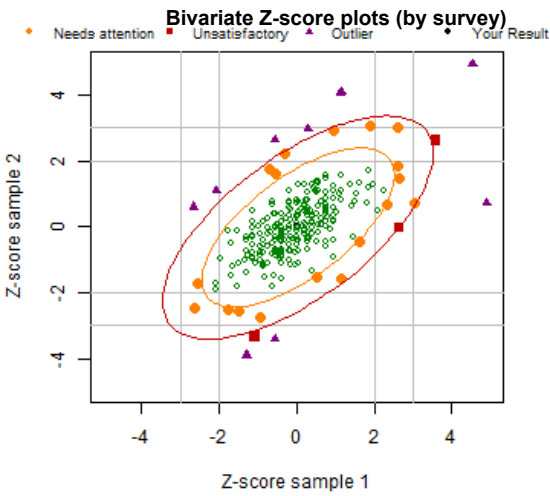
Z-score history (by survey)



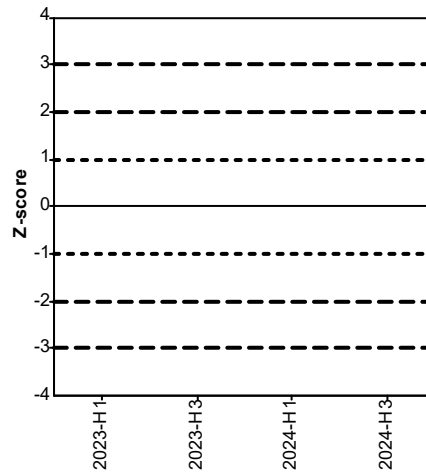
Z-score history (by consensus value)



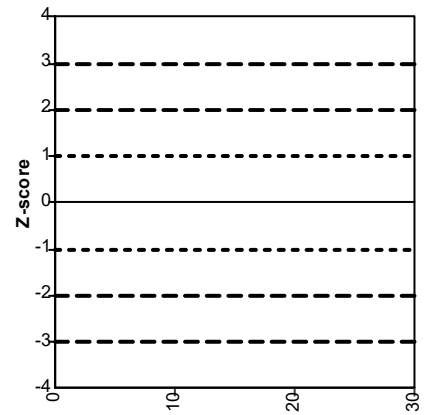
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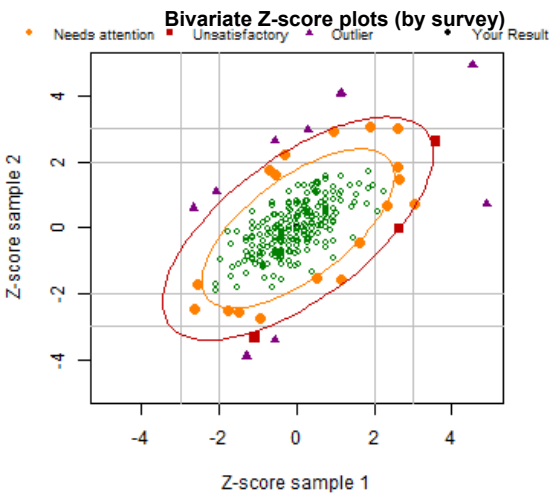
Z-score history (by survey)



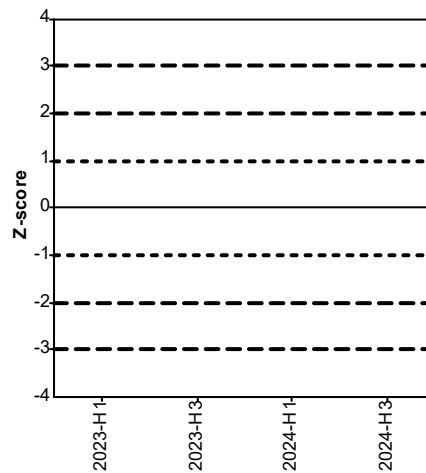
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

