

# ECAT FOUNDATION

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## REPORT



**SURVEY 2024-H1**

**Haemophilia**

**Labcode 1492**

Date of Issue : 22-April-2024

Survey : 2024-H1

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 **June 21st, 2024**.

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

##### **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.

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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**OVERVIEW Z-SCORES**

UV: Satisfactory ( $-2 \leq Z\text{-score} \leq 2$ )  
 BV: Acceptable
  UV: Need attention ( $-3 < Z\text{-score} < -2$  or  $2 < Z\text{-score} < 3$ )  
 BV: Questionable
  UV: Unsatisfactory ( $Z\text{-score} \leq -3$  or  $\geq 3$ )  
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor IX Inhibitor	Factor IX Inhibitor	24.61	1	<span style="background-color: green;">0.77</span>	<span style="background-color: green;">0.86</span>	<span style="background-color: green;">0.76</span>	<span style="background-color: green;"></span>
		24.62	1	<span style="background-color: green;">0.39</span>	<span style="background-color: green;">0.37</span>	<span style="background-color: green;">0.38</span>	<span style="background-color: green;"></span>

<b>Factor IX Inhibitor</b>	<b>Factor IX Inhibitor</b>
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<b>Sample No</b>	24.61		
<b>Sample Details</b>	Plasma with a Factor IX Inhibitor level of approx. 6.0 BU/mL		
<b>Prior Use</b>	None		
<b>Unit</b>	BU/mL		
<b>Expiry Date</b>	30-September-2026		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	FIX inhibitor
<b>Number of Participants</b>	268		
<b>Number of Responders</b>	254	<b>Response Rate</b>	95 %
<b>Comments</b>	The following participant reported a deviating result which was excluded in the statistical evaluation: <b>913</b> : 0.67 BU/mL		

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 samples 24.61 and 24.62:  
**176** : 0.9 BU/mL

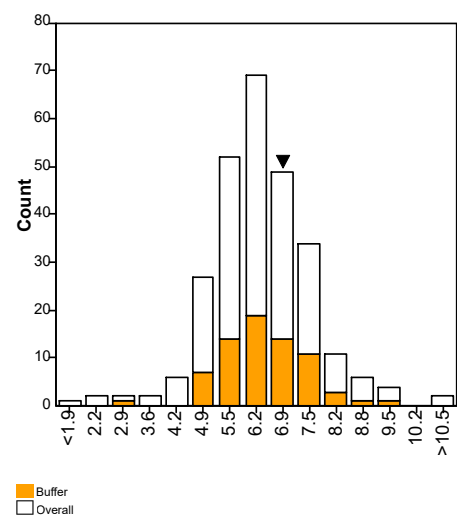
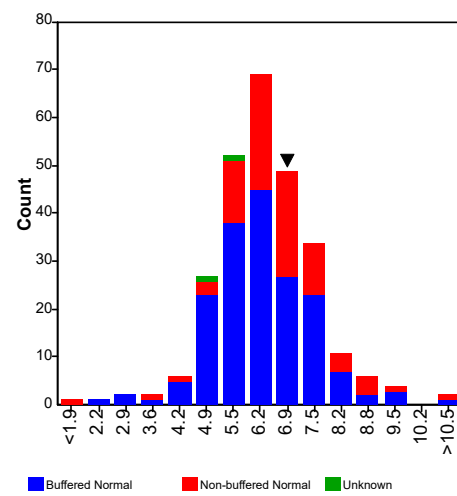
The following participants submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis:  
**3816**  
**3828**

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	267	6.3	0.08	16.8	1.6 - 18.4	7.1	0.77				
<b>Buffered Normal Pooled Plasma</b>	179	6.2	0.10	17.3	1.9 - 15.2	7.1	0.86				
Buffer	71	6.4	0.15	15.6	3.0 - 9.5	7.1	0.76				

**Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	267	6.3	0.08	16.8	1.6 - 18.4
<b>Unknown</b>	2	5.1			4.8 - 5.4
Factor IX deficient plasma	1	5.4			-
Other	1	4.8			-
<b>Buffered Normal Pooled Plasma</b>	179	6.2	0.10	17.3	1.9 - 15.2
Buffer + Albumin	20	6.2	0.31	17.9	4.0 - 9.2
Factor IX deficient plasma	72	6.0	0.15	17.4	2.4 - 15.2
Heat-inactivated normal plasma	7	5.9			1.9 - 8.3
Other	8	6.7			5.1 - 8.4
Unknown	1	5.5			-
<b>Non-buffered Normal Pooled Plasma</b>	86	6.5	0.13	15.0	1.6 - 18.4
Buffer	46	6.7	0.17	13.9	4.6 - 9.6
Buffer + Albumin	2	7.9			6.9 - 9.0
Factor IX deficient plasma	24	6.5	0.26	15.5	1.6 - 18.4
Heat-inactivated normal plasma	2	7.4			5.9 - 8.8
Other	10	5.8	0.35	15.2	4.5 - 7.0
Unknown	2	6.1			6.0 - 6.1



<b>Factor IX Inhibitor</b>	<b>Factor IX Inhibitor</b>
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**Sample No** 24.62  
**Sample Details** Plasma with a Factor IX Inhibitor level of approx. 0.8 BU/mL  
**Prior Use** None  
**Unit** BU/mL  
**Expiry Date** 30-September-2026  
**Homogeneity** 2.1 % **Homogeneity Parameter** FIX inhibitor  
 For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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** 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 samples 24.61 and 24.62:  
**176** : 5.2 BU/mL

The following participants submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis:

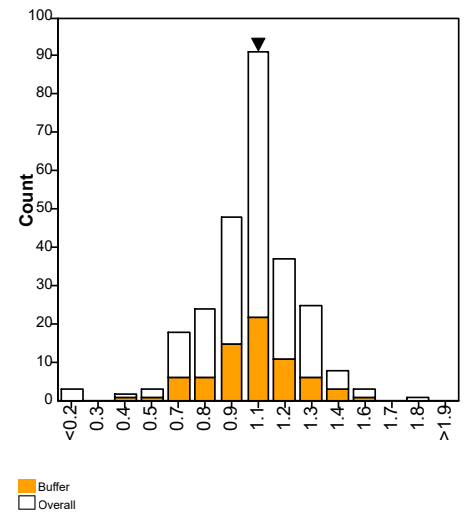
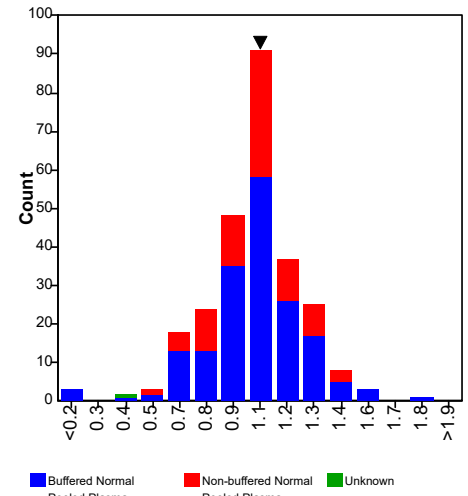
**3816**  
**3828**

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	263	1.0	0.02	19.7	0.0 - 1.9	1.1	0.39				
<b>Buffered Normal Pooled Plasma</b>	177	1.0	0.02	20.4	0.0 - 1.9	1.1	0.37				
Buffer	72	1.0	0.03	21.0	0.4 - 1.5	1.1	0.38				

**Other Reagents**

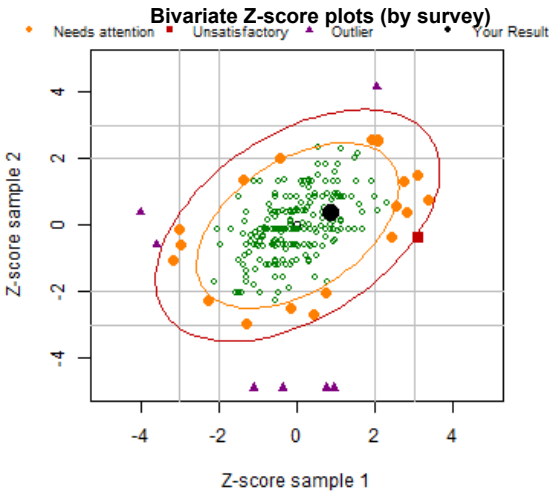
	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	263	1.0	0.02	19.7	0.0 - 1.9
<b>Unknown</b>	1	0.4			-
<b>Other</b>	1	0.4			-
<b>Buffered Normal Pooled Plasma</b>	177	1.0	0.02	20.4	0.0 - 1.9
<b>Buffer + Albumin</b>	19	1.0	0.05	18.4	0.6 - 1.3
<b>Factor IX deficient plasma</b>	70	1.0	0.03	21.9	0.0 - 1.9
<b>Heat-inactivated normal plasma</b>	8	1.1			0.8 - 1.2
<b>Other</b>	7	1.0			0.8 - 1.6
<b>Unknown</b>	1	0.9			-
<b>Non-buffered Normal Pooled Plasma</b>	85	1.0	0.03	18.3	0.5 - 1.5
<b>Buffer</b>	45	1.1	0.04	18.9	0.5 - 1.5
<b>Buffer + Albumin</b>	2	1.0			0.8 - 1.1
<b>Factor IX deficient plasma</b>	24	1.0	0.03	12.3	0.7 - 1.3
<b>Heat-inactivated normal plasma</b>	2	1.1			1.1 - 1.2
<b>Other</b>	10	0.8	0.08	23.5	0.6 - 1.1
<b>Unknown</b>	2	0.9			0.8 - 0.9



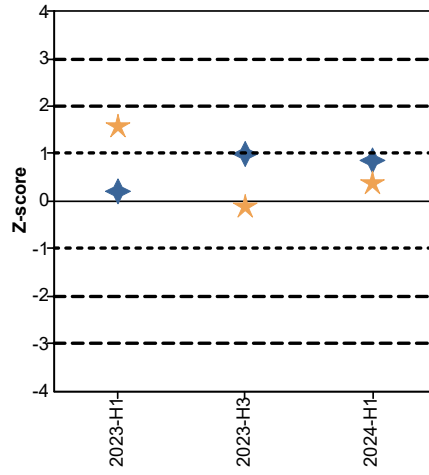
**Factor IX Inhibitor**

**Factor IX Inhibitor**

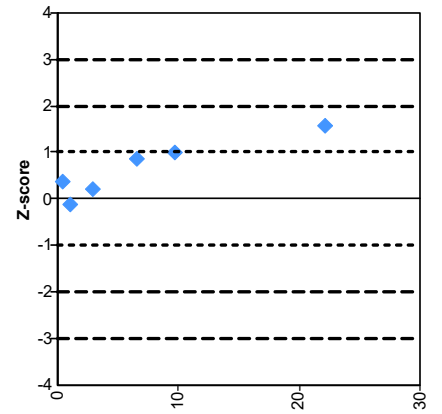
Instrument ID



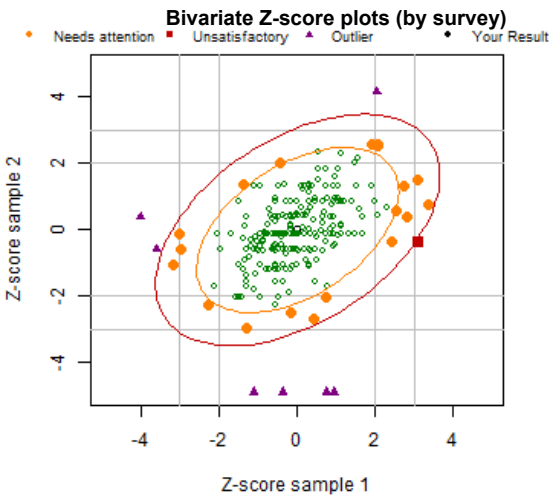
Z-score history (by survey)



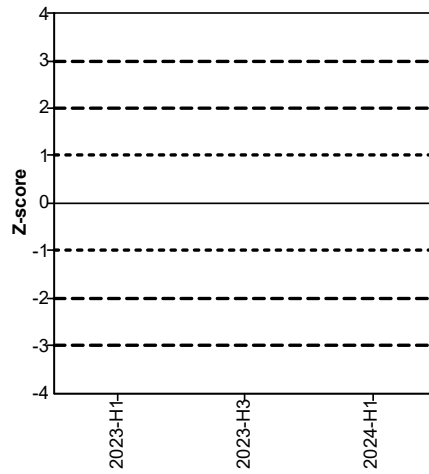
Z-score history (by consensus value)



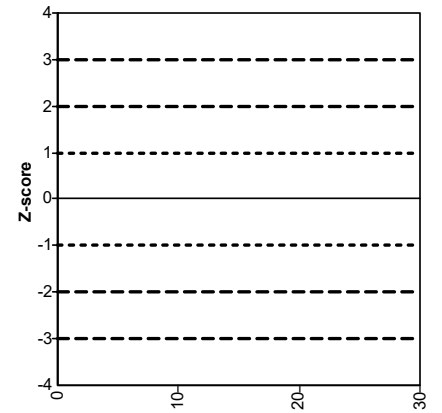
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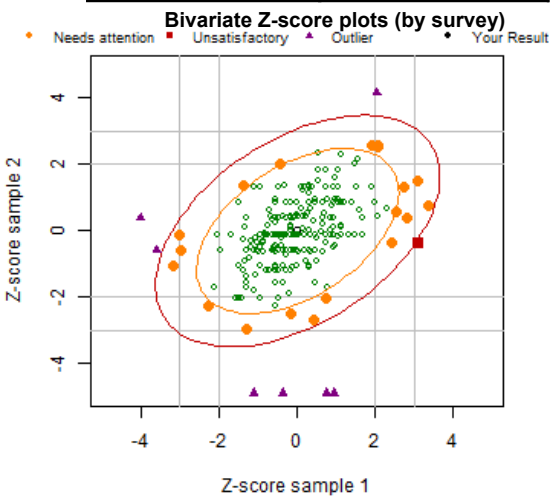
Z-score history (by survey)



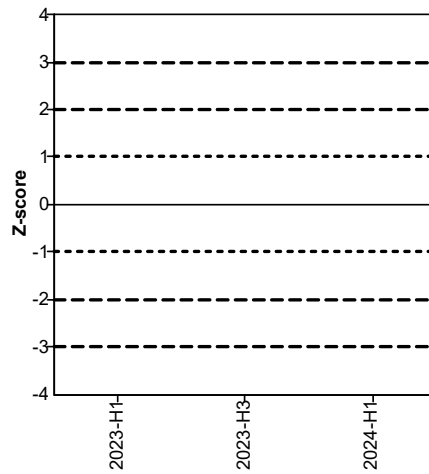
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

