

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2023-H3**

**Haemophilia**

**Labcode 1492**

Date of Issue : 27-oktober-2023

Survey : 2023-H3

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 **December 12th, 2023**.

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

##### **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.

This report is authorized by:

Dr. M.J. van Essen-Hollestelle  
Programme Expert

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

Director: Dr. P. Meijer  
ECAT Office  
P.O. Box 107  
2250 AC Voorschoten, The Netherlands  
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919  
E-mail: [info@ecat.nl](mailto:info@ecat.nl)  
Website: [www.ecat.nl](http://www.ecat.nl)  
VAT number: NL802836872B01

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  $\geq 3$ )
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor IX Inhibitor	Factor IX Inhibitor	23.162	1	0.89	1.00	1.24	
		23.163	1	-0.12	-0.12	-0.05	

**Factor IX Inhibitor**

Sample No	23.162		
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 9 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-april-2026		
Homogeneity	0.0 %	Homogeneity Parameter	FIX inhibitor
Number of Participants	277		
Number of Responders	246	Response Rate	89 %
Comments	The following participant reported a deviating result which was excluded in the statistical evaluation: <b>792</b> : 1.05 BU/mL		

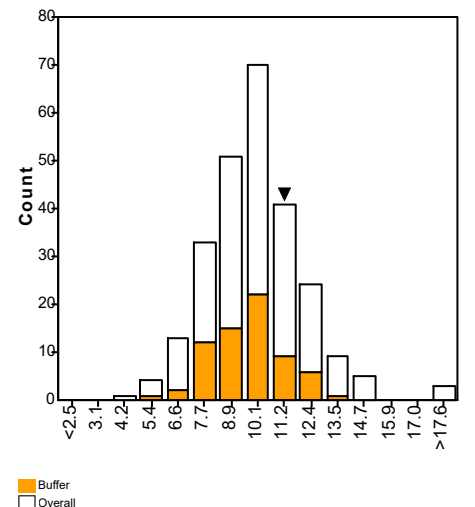
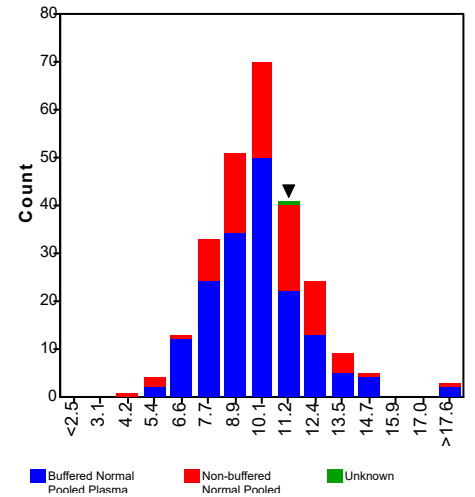
The following participants (**labcodes: 192, 213, 1022, 1077 and 3810**) reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the sample 23.162 and 23.163.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	254	9.9	0.14	18.7	4.7 - 35.2	11.5	0.89				
Buffered Normal Pooled Plasma	168	9.7	0.17	18.7	5.8 - 35.2	11.5	1.00				
Buffer	68	9.6	0.23	15.8	5.8 - 13.2	11.5	1.24				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	254	9.9	0.14	18.7	4.7 - 35.2
Unknown	1	11.3			-
Factor IX deficient plasma	1	11.3			-
Buffered Normal Pooled Plasma	168	9.7	0.17	18.7	5.8 - 35.2
Buffer + Albumin	19	9.5	0.52	19.2	6.2 - 12.2
Factor IX deficient plasma	67	10.2	0.31	20.0	6.5 - 35.2
Heat-inactivated normal plasma	7	7.0			5.8 - 13.2
Other	6	8.5			7.2 - 9.6
Unknown	1	6.4			-
Non-buffered Normal Pooled Plasma	85	10.1	0.25	18.4	4.7 - 18.9
Buffer	47	9.9	0.34	19.0	4.7 - 14.7
Buffer + Albumin	2	11.9			11.8 - 12.1
Factor IX deficient plasma	26	10.1	0.42	16.8	5.9 - 18.9
Heat-inactivated normal plasma	2	12.7			11.8 - 13.6
Other	7	9.4			8.0 - 12.8
Unknown	1	11.0			-



<b>Factor IX Inhibitor</b>	<b>Factor IX Inhibitor</b>
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<b>Sample No</b>	23.163		
<b>Sample Details</b>	Plasma with a Factor IX Inhibitor level of approx. 1 BU/mL		
<b>Prior Use</b>	None		
<b>Unit</b>	BU/mL		
<b>Expiry Date</b>	30-april-2026		
<b>Homogeneity</b>	3.3 %	<b>Homogeneity Parameter</b>	FIX inhibitor
For any method used for the measurement of this parameter with a CV ≤ 11.0% 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.			
<b>Number of Participants</b>	277		
<b>Number of Responders</b>	246	<b>Response Rate</b>	89 %
<b>Comments</b>	The following participant reported a deviating result which was excluded in the statistical evaluation: <b>143</b> : 46.8 BU/mL		

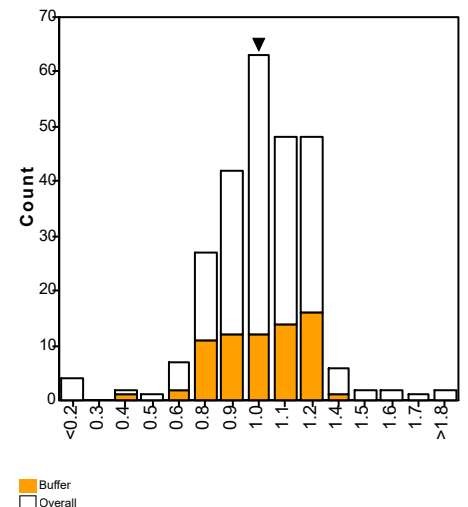
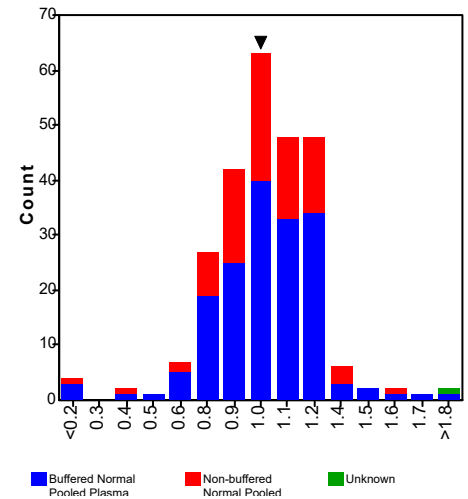
The following participants (**labcodes: 192, 213, 1022, 1077 and 3810**) reported deviating results which were excluded in the statistical evaluation. These results might be caused by an accidental mix-up of the sample 23.162 and 23.163.

**Own Reagent**

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
<b>Total Group</b>	255	1.0	0.02	19.5	0.0 - 4.0	1.0	-0.12				
<b>Buffered Normal Pooled Plasma</b>	169	1.0	0.02	19.8	0.0 - 4.0	1.0	-0.12				
<b>Buffer</b>	69	1.0	0.03	21.3	0.4 - 1.4	1.0	-0.05				

**Other Reagents**

	n	assigned value	Uncert.	CV (%)	Range
<b>Total Group</b>	255	1.0	0.02	19.5	0.0 - 4.0
<b>Unknown</b>	1	2.9			-
<b>Factor IX deficient plasma</b>	1	2.9			-
<b>Buffered Normal Pooled Plasma</b>	169	1.0	0.02	19.8	0.0 - 4.0
<b>Buffer + Albumin</b>	18	1.0	0.04	12.3	0.7 - 1.3
<b>Factor IX deficient plasma</b>	68	1.1	0.03	19.4	0.0 - 4.0
<b>Heat-inactivated normal plasma</b>	7	1.0			0.7 - 1.2
<b>Other</b>	6	0.9			0.0 - 1.1
<b>Unknown</b>	1	0.8			-
<b>Non-buffered Normal Pooled Plasma</b>	85	1.0	0.03	18.9	0.0 - 1.6
<b>Buffer</b>	47	1.0	0.03	17.4	0.4 - 1.3
<b>Buffer + Albumin</b>	2	1.0			0.8 - 1.3
<b>Factor IX deficient plasma</b>	26	1.0	0.04	17.8	0.0 - 1.3
<b>Heat-inactivated normal plasma</b>	2	1.4			1.2 - 1.6
<b>Other</b>	7	1.0			0.7 - 1.4
<b>Unknown</b>	1	1.0			-



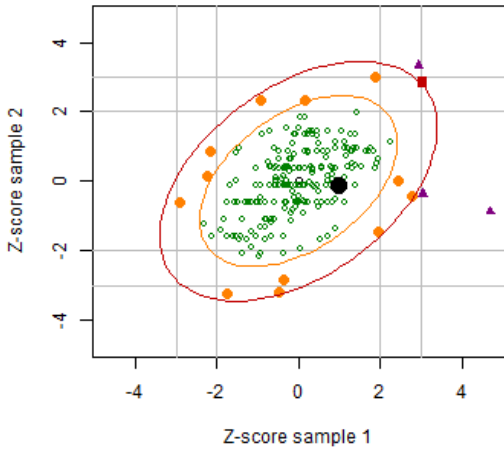
**Factor IX Inhibitor**

**Factor IX Inhibitor**

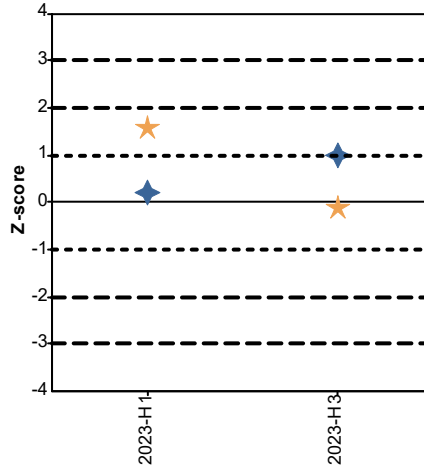
Instrument ID

**Bivariate Z-score plots (by survey)**

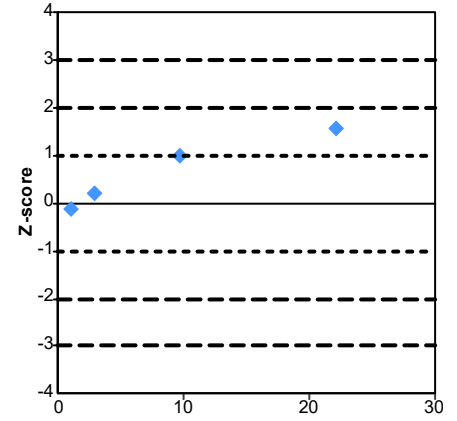
Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



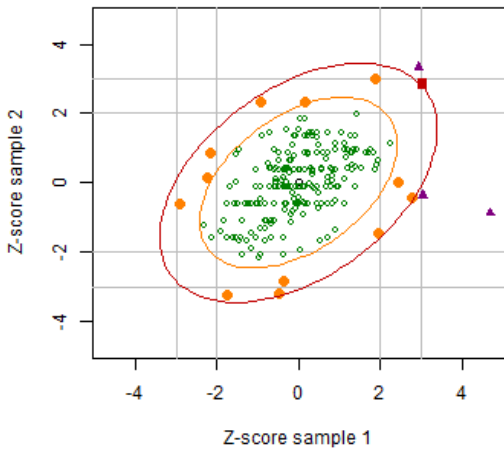
**Z-score history (by consensus value)**



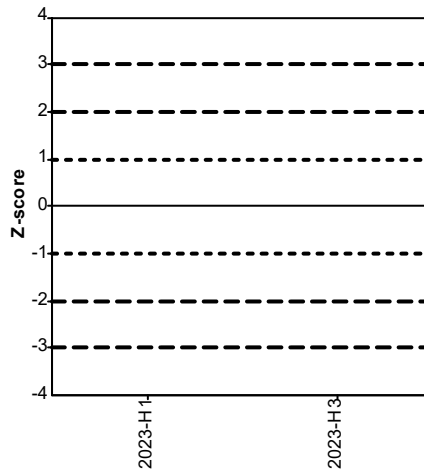
Instrument ID

**Bivariate Z-score plots (by survey)**

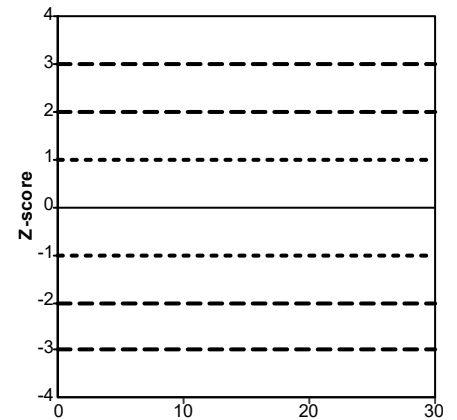
Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



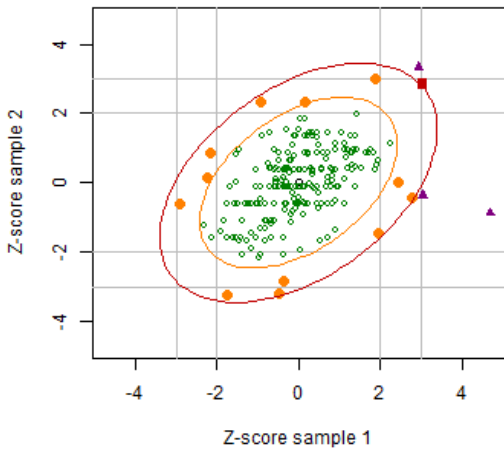
**Z-score history (by consensus value)**



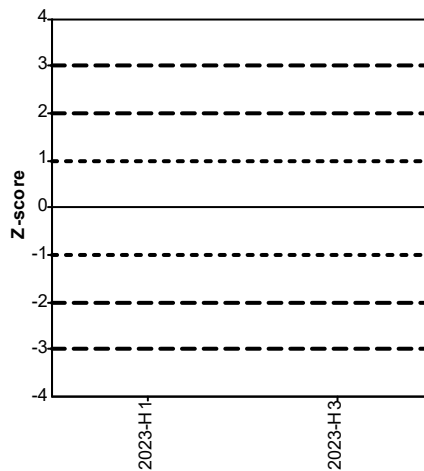
Instrument ID

**Bivariate Z-score plots (by survey)**

Needs attention Unsatisfactory Outlier Your Result



**Z-score history (by survey)**



**Z-score history (by consensus value)**

