

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-H2

Haemophilia

Labcode 1492

Date of Issue : 07-July-2023

Survey : 2023-H2

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 **September 22nd, 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.

Participants in Factor VIII Inhibitor module

In the Factor VIII (FVIII) Inhibitor module a new parameter is introduced: Factor VIII Inhibitor (by type of test). The purpose is to discriminate between commercially available FVIII inhibitor tests (e.g. Precision Biologics, Technoclone) and lab-developed tests. A "Lab-developed test" is when you have set-up the inhibitor test in your own laboratory and not using a commercial available test. It is not the meaning to select Commercial Test because you use commercial reagents for the measurement of the residual FVIII. The option "Other" within the selection "Commercial Test" is most likely selected by a large group of participants because of the use of commercial reagents for FVIII determination. Please be aware to select the correct option, if not a commercial FVIII Inhibitor Test is used, the option "Lab-developed test" should be selected.

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

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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 VIII inhibitor	Factor VIII Inhibitor (by inhibitor assay conc)	23.104	1	-1.54	-1.58	-1.58	-1.92	
		23.105	1	-1.48	-1.49	-1.49	-1.63	
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	23.104	1	-1.54	-1.26	-1.26	-1.03	
		23.105	1	-1.48	-1.17	-1.17	-1.14	
Factor VIII inhibitor	Factor VIII Inhibitor (Manufacturer)	23.104	1	-1.54	-1.54	-1.54		
		23.105	1	-1.48	-1.47	-1.47		

Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 23.104
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 11 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-December-2024
Homogeneity 4.6 % **Homogeneity Parameter** FVIII inhibitor
 For any method used for the measurement of this parameter with a **CV ≤ 15.3%** 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 352
Number of Responders 326 **Response Rate** 93 %
Comments Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The option “Other” within the selection “Commercial Test” is most likely selected by a large group of participants because of the use of commercial reagents for FVIII determination. Please be aware to select the correct option, if not a commercial FVIII Inhibitor Test is used, the option “Lab-developed test” should be selected.

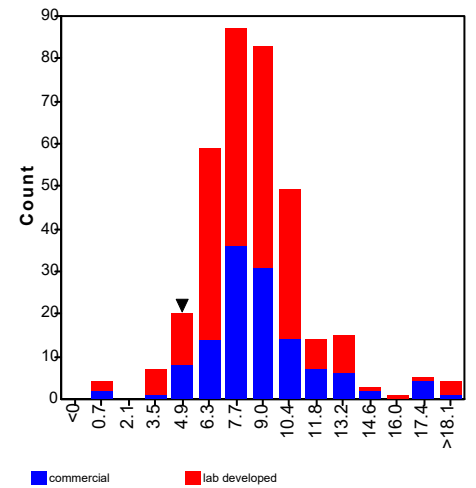
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Lab-developed test	225	8.3	0.18	25.6	0.9 - 35.2	5.0	-1.54				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Commercial Test	126	8.6	0.27	27.8	1.1 - 20.0
Other	67	8.5	0.45	34.3	1.1 - 20.0
Precision Biologics	22	8.5	0.45	19.9	3.3 - 16.8
Technoclone	37	8.7	0.41	23.0	5.1 - 13.4
Lab-developed test	225	8.3	0.18	25.6	0.9 - 35.2



Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 23.105
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 3.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-December-2024
Homogeneity 6.8 % **Homogeneity Parameter** FVIII inhibitor
 For any method used for the measurement of this parameter with a CV ≤ 22.7% 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.

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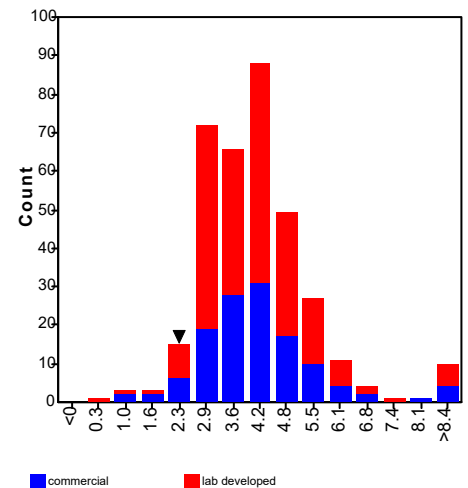
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Lab-developed test	225	4.0	0.09	27.1	0.0 - 34.5	2.4	-1.47				

Other Reagents

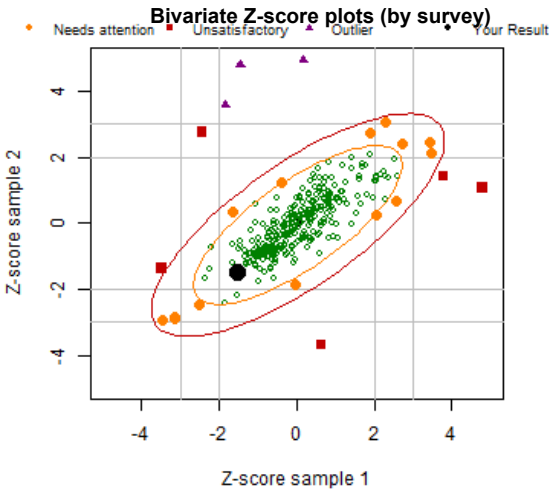
	n	assigned value	Uncert.	CV (%)	Range
Commercial Test	126	4.0	0.12	27.2	0.9 - 9.7
Other	67	4.0	0.18	29.7	0.9 - 9.7
Precision Biologics	22	4.0	0.19	17.9	2.9 - 6.7
Technoclone	37	4.1	0.25	30.2	2.2 - 7.0
Lab-developed test	225	4.0	0.09	27.1	0.0 - 34.5



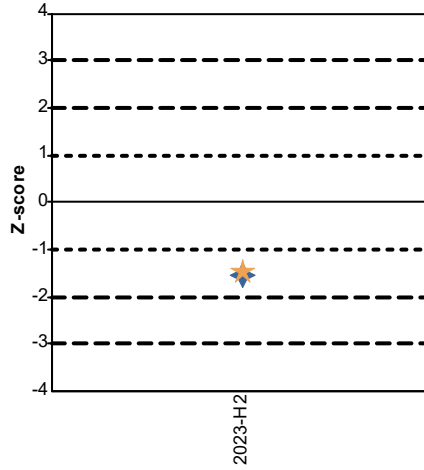
Factor VIII inhibitor

Factor VIII Inhibitor (by type of test)

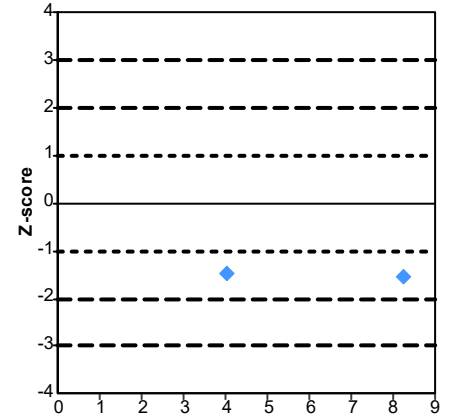
Instrument ID



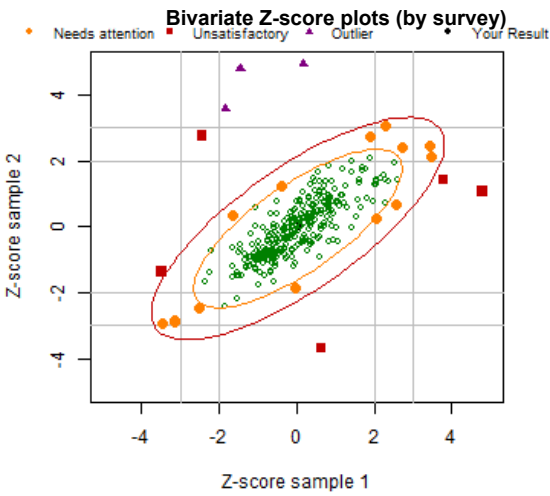
Z-score history (by survey)



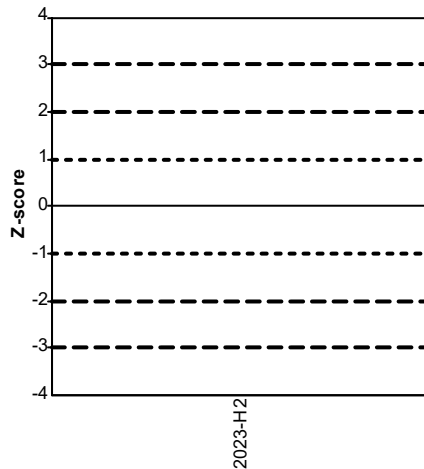
Z-score history (by consensus value)



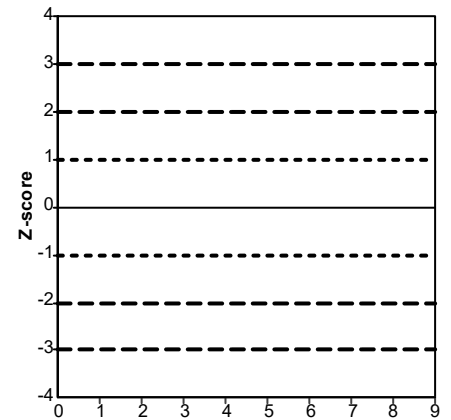
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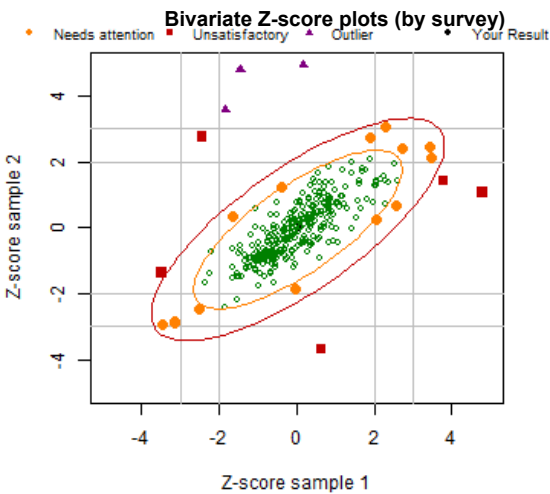
Z-score history (by survey)



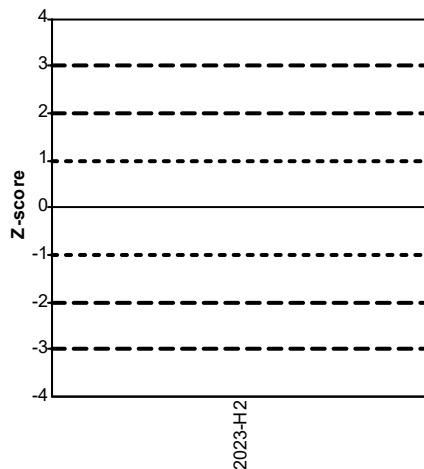
Z-score history (by consensus value)



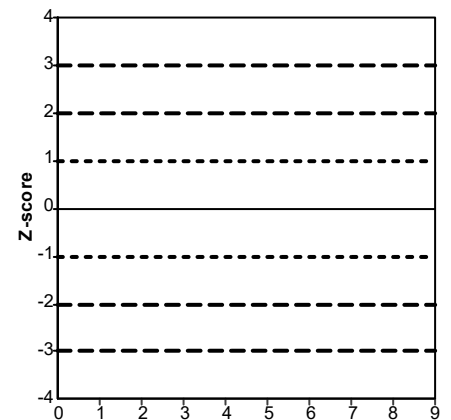
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor	Factor VIII Inhibitor (by inhibitor assay concept)
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Sample No	23.104		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 11 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-December-2024		
Homogeneity	4.6 %	Homogeneity Parameter	FVIII inhibitor
For any method used for the measurement of this parameter with a CV ≤ 15.3% 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	352		
Number of Responders	326	Response Rate	93 %
Comments	Participant 3828 submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.		

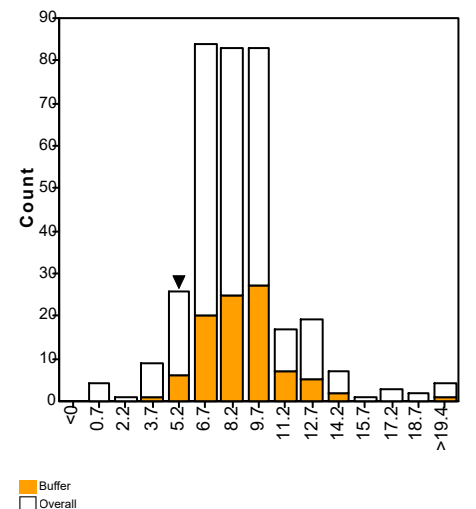
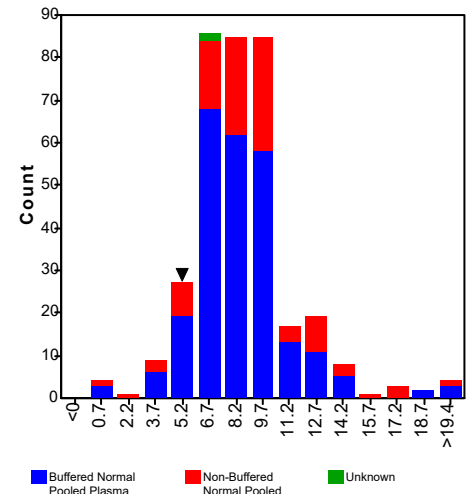
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Buffered Normal Pooled Plasma	250	8.2	0.16	24.8	0.9 - 35.2	5.0	-1.58				
Buffer	94	8.7	0.25	22.1	4.2 - 32.0	5.0	-1.92				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Non-Buffered Normal Pooled Plasma	99	8.8	0.33	30.4	1.1 - 20.0
Buffer	54	9.2	0.46	29.1	2.9 - 20.0
Buffer + Albumin	2	10.4			9.9 - 10.9
Factor VIII Deficient Plasma	21	8.0	0.81	37.1	1.1 - 15.6
Heat-activated normal plasma	3	9.0			6.7 - 17.6
Other	11	8.6	0.77	24.0	6.2 - 14.0
Unknown	4	6.4			4.2 - 10.0
Buffered Normal Pooled Plasma	250	8.2	0.16	24.8	0.9 - 35.2
Buffer + Albumin	25	9.0	0.44	19.7	5.8 - 21.4
Factor VIII Deficient Plasma	97	7.6	0.26	27.1	0.9 - 14.0
Heat-inactivated normal plasma	17	7.6	0.50	21.8	0.9 - 11.8
Other	12	9.1	0.86	26.2	6.0 - 35.2
Unknown	1	13.7			-
Unknown	2	7.1			7.0 - 7.2
Buffer	1	7.2			-
Factor VIII Deficient Plasma	1	7.0			-



Factor VIII inhibitor	Factor VIII Inhibitor (by inhibitor assay concept)
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Sample No	23.105		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 3.5 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-December-2024		
Homogeneity	6.8 %	Homogeneity Parameter	FVIII inhibitor
For any method used for the measurement of this parameter with a CV ≤ 22.7% 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.			
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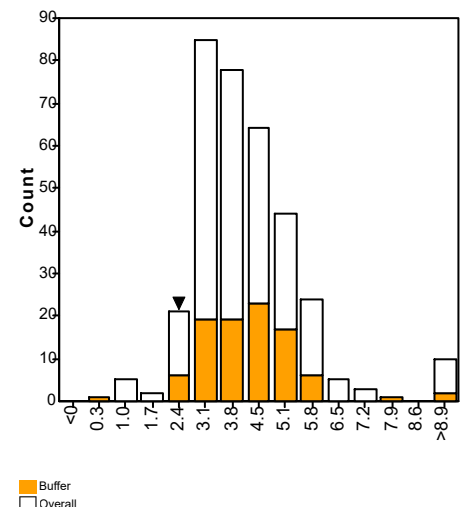
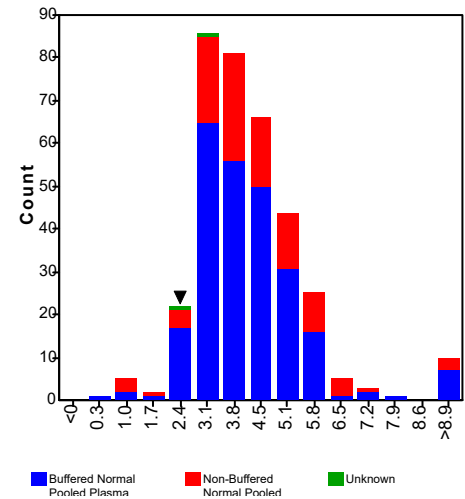
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Buffered Normal Pooled Plasma	250	3.9	0.08	26.4	0.0 - 34.5	2.4	-1.49				
Buffer	94	4.1	0.13	25.1	0.0 - 32.0	2.4	-1.63				

Other Reagents

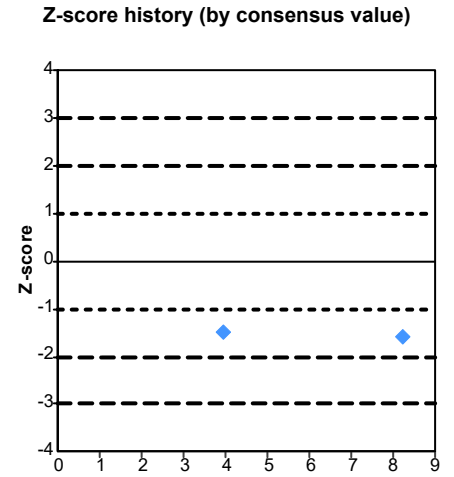
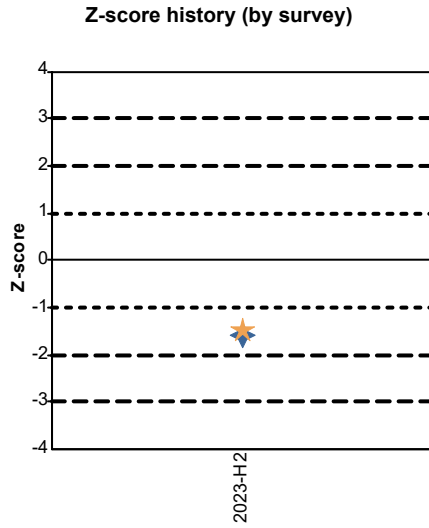
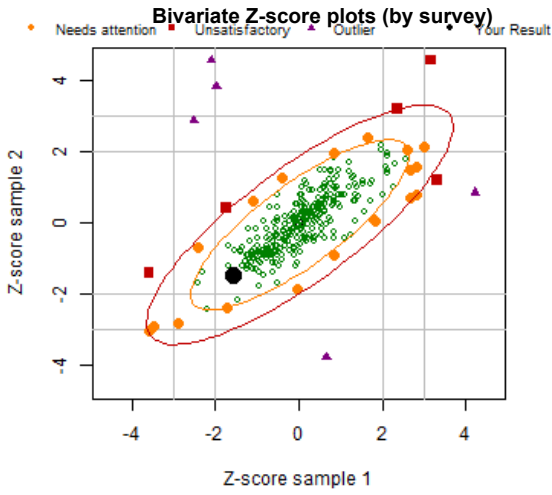
	n	assigned value	Uncert.	CV (%)	Range
Non-Buffered Normal Pooled Plasma	99	4.2	0.15	28.2	0.9 - 11.1
Buffer	54	4.4	0.19	25.8	1.3 - 9.6
Buffer + Albumin	2	4.5			4.3 - 4.8
Factor VIII Deficient Plasma	21	3.8	0.39	37.7	0.9 - 11.1
Heat-activated normal plasma	3	5.4			3.3 - 5.6
Other	11	3.9	0.35	23.7	2.9 - 6.6
Unknown	4	2.8			1.4 - 5.0
Buffered Normal Pooled Plasma	250	3.9	0.08	26.4	0.0 - 34.5
Buffer + Albumin	25	4.4	0.33	29.8	2.9 - 10.5
Factor VIII Deficient Plasma	97	3.8	0.13	27.2	0.8 - 34.5
Heat-inactivated normal plasma	17	3.7	0.27	24.0	2.5 - 5.5
Other	12	4.1	0.39	26.6	2.5 - 5.6
Unknown	1	5.5			-
Unknown	2	2.9			2.6 - 3.2
Buffer	1	3.2			-
Factor VIII Deficient Plasma	1	2.6			-



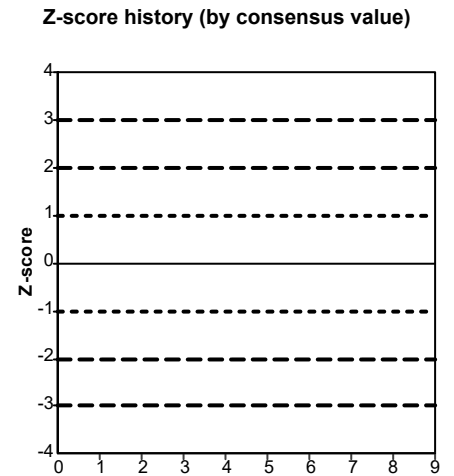
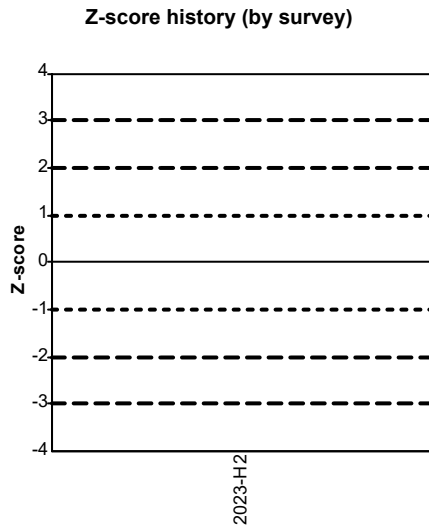
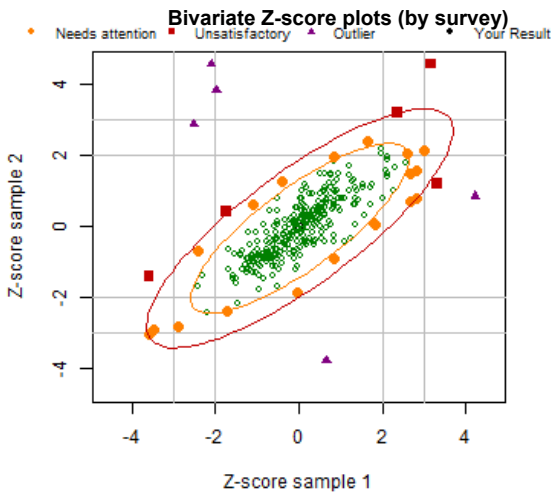
Factor VIII inhibitor

Factor VIII Inhibitor (by inhibitor assay concept)

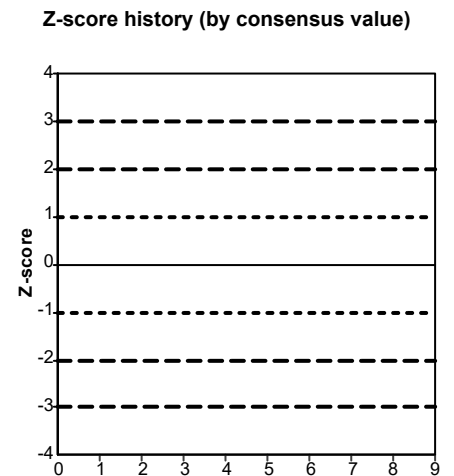
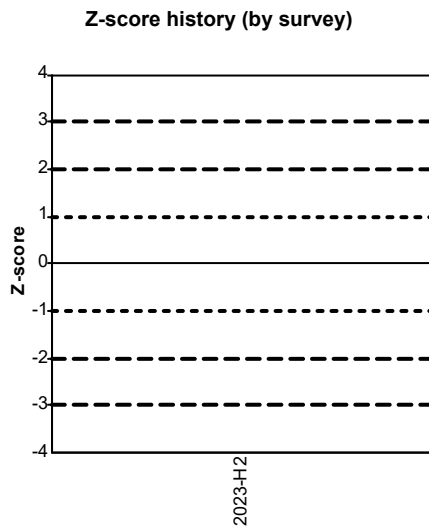
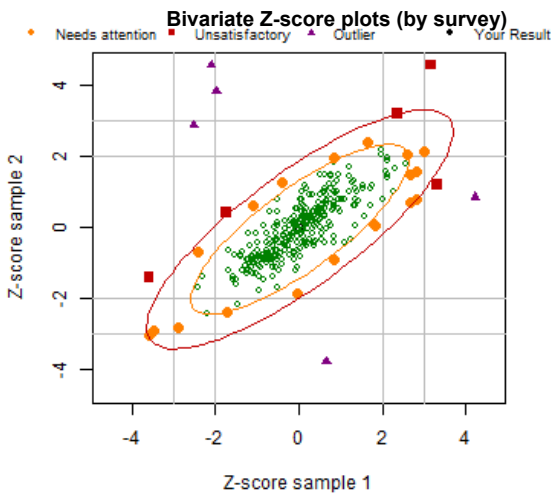
Instrument ID



Instrument ID



Instrument ID



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No	23.104		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 11 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-December-2024		
Homogeneity	4.6 %	Homogeneity Parameter	FVIII inhibitor
For any method used for the measurement of this parameter with a CV ≤ 15.3% 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.			
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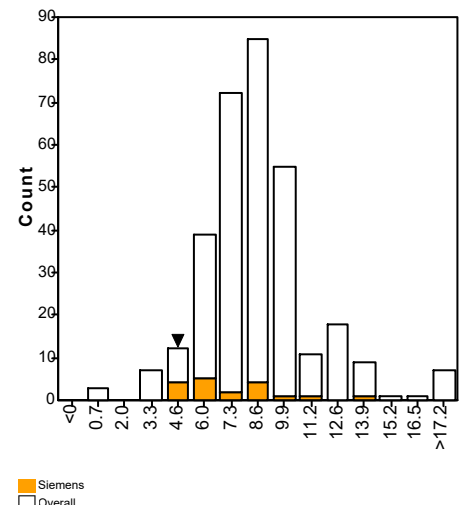
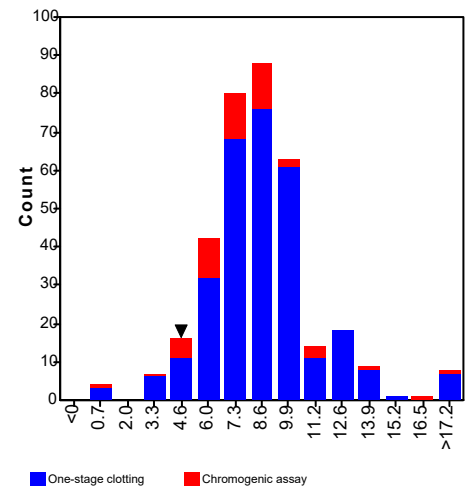
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Chromogenic assay	49	7.5	0.36	26.6	0.9 - 17.2	5.0	-1.26				
Siemens Factor VIII	18	7.3	0.67	30.9	4.2 - 13.7	5.0	-1.03				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
One-stage clotting assay	302	8.5	0.16	25.5	0.9 - 35.2
Hemoliance Synthasil APTT	1	17.9			-
Hyphen Biomed Cephen	1	13.5			-
IL HemosIL APTT lyophilised silica	3	8.2			7.3 - 12.4
IL HemosIL APTT-SP liquid silica	5	7.6			5.6 - 8.1
IL HemosIL SynthASil	100	8.9	0.32	28.9	3.2 - 35.2
Other	1	4.7			-
Roche APTT	2	8.4			7.7 - 9.0
Siemens Actin FS	46	7.9	0.33	22.8	3.5 - 14.0
Siemens Actin FSL	10	8.5	0.29	8.5	6.4 - 14.0
Siemens Pathromtin SL	40	9.1	0.53	29.8	1.1 - 20.0
Stago Cephalin/Kaolin/CK Prest	43	8.5	0.29	18.2	3.1 - 10.7
Stago Cephascreen	2	7.7			5.4 - 10.0
Stago PTT (automate)	12	9.4	1.01	30.0	1.1 - 12.9
Tcoag Automated APTT	1	9.0			-
Tcoag TriniClot APTT S	2	4.2			2.9 - 5.5
Tcoag TriniClot APTT-HS	3	8.0			6.5 - 8.9
Technoclone Dapttin	1	8.6			-
Technoclone Siron LS	1	8.5			-
Chromogenic assay	49	7.5	0.36	26.6	0.9 - 17.2
Chromogenix Coamatic Factor VIII	11	6.9	0.57	21.8	0.9 - 9.4
Chromogenix Coatest SP Factor VIII	3	6.0			6.0 - 6.1
Hyphen Biomed Biophen Factor VIII	1	16.8			-
IL Electrachrome FVIII	2	12.9			8.6 - 17.2
Other	2	7.0			7.0 - 7.1
Precision Biologic Cryocheck Chromog	5	8.0			3.3 - 9.1
TCoag Trinichrom FVIII	1	11.5			-
Technoclone Factor VIII	3	8.5			7.3 - 8.9



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No 23.105
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 3.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-December-2024
Homogeneity 6.8 % **Homogeneity Parameter** FVIII inhibitor
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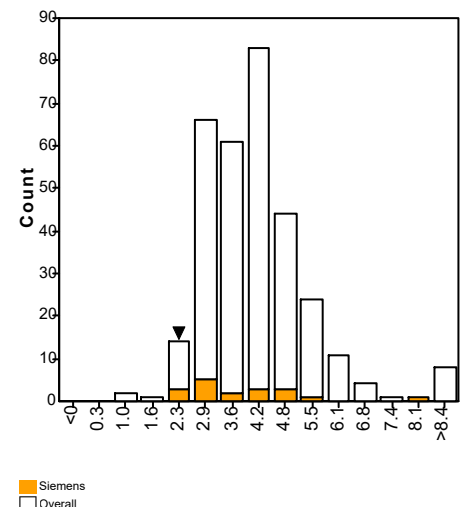
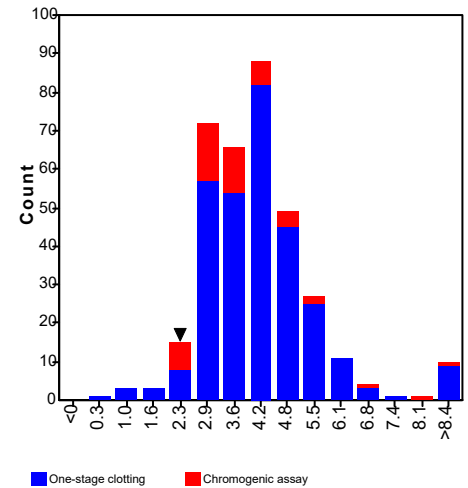
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Chromogenic assay	49	3.5	0.17	27.1	2.1 - 9.6	2.4	-1.17				
Siemens Factor VIII	18	3.8	0.35	31.6	2.4 - 8.0	2.4	-1.14				

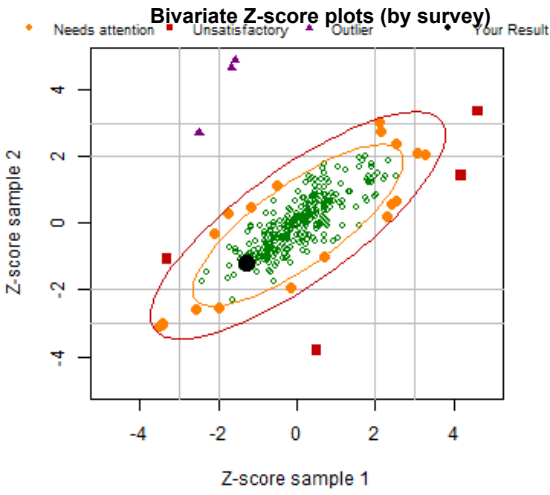
Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
One-stage clotting assay	302	4.1	0.08	26.2	0.0 - 34.5
Hemoliance Synthasil APTT	1	9.7			-
Hyphen Biomed Cephen	1	4.3			-
IL HemosIL APTT lyophilised silica	3	3.5			3.3 - 4.8
IL HemosIL APTT-SP liquid silica	5	3.3			2.8 - 4.5
IL HemosIL SynthASil	100	4.3	0.16	29.7	2.0 - 10.5
Other	1	4.4			-
Roche APTT	2	3.7			3.0 - 4.4
Siemens Actin FS	46	3.8	0.17	24.1	2.4 - 34.5
Siemens Actin FSL	10	4.5	0.26	14.8	3.3 - 5.4
Siemens Pathromtin SL	40	4.3	0.23	27.9	0.9 - 6.1
Stago Cephalin/Kaolin/CK Prest	43	4.0	0.14	18.3	2.2 - 7.0
Stago Cephascreen	2	3.8			2.9 - 4.7
Stago PTT (automate)	12	4.4	0.27	16.9	0.9 - 5.4
Tcoag Automated APTT	1	4.0			-
Tcoag TriniClot APTT S	2	2.0			1.3 - 2.7
Tcoag TriniClot APTT-HS	3	4.0			3.1 - 4.9
Technoclone Dapttin	1	3.9			-
Technoclone Siron LS	1	3.7			-
Chromogenic assay	49	3.5	0.17	27.1	2.1 - 9.6
Chromogenix Coamate Factor VIII	11	3.0	0.25	21.7	2.1 - 4.4
Chromogenix Coatest SP Factor VIII	3	2.9			2.6 - 2.9
Hyphen Biomed Biophen Factor VIII	1	6.7			-
IL Electrachrome FVIII	2	6.5			3.5 - 9.6
Other	2	2.8			2.5 - 3.0
Precision Biologic Cryocheck Chromog	5	3.2			3.0 - 4.6
TCoag Trinichrom FVIII	1	4.3			-
Technoclone Factor VIII	3	3.7			3.5 - 4.3

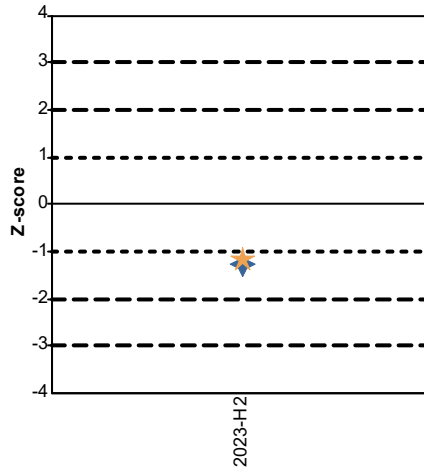


Factor VIII inhibitor **Factor VIII Inhibitor (by FVIII assay)**

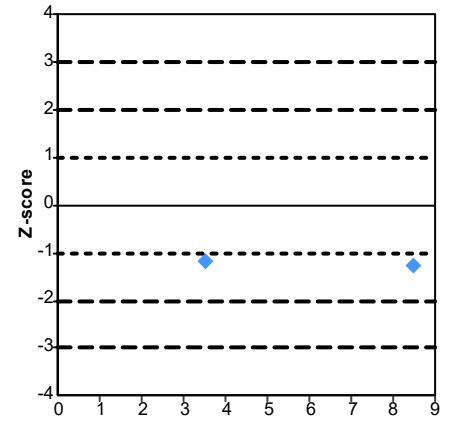
Instrument ID



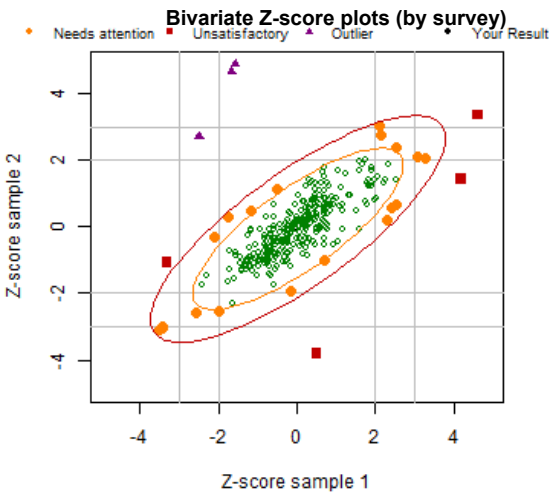
Z-score history (by survey)



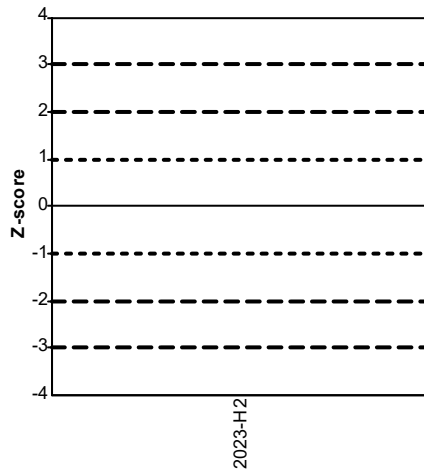
Z-score history (by consensus value)



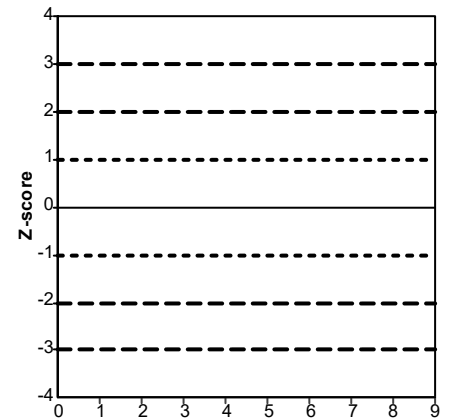
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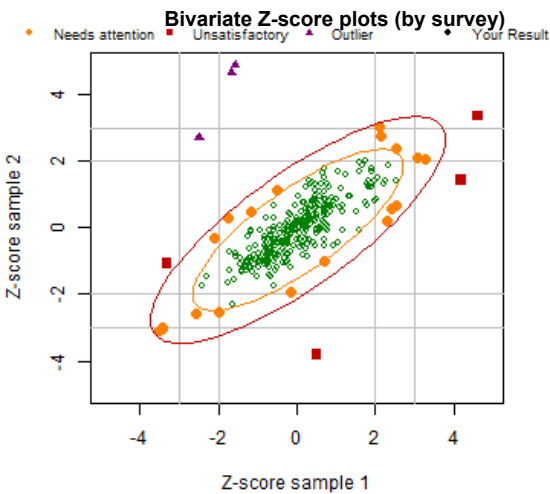
Z-score history (by survey)



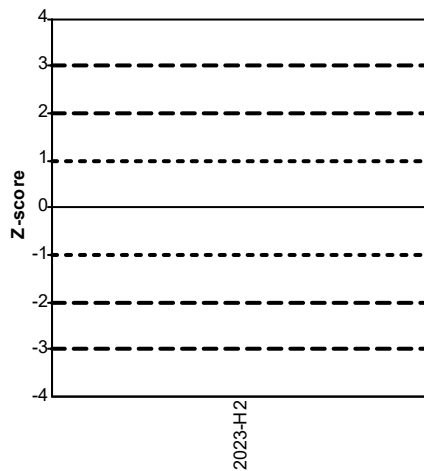
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

