

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-H4

Haemophilia

Labcode 1492

Date of Issue : 13-January-2025

Survey : 2024-H4

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

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.

Emicizumab, Esperoct, NovoEight and Refixia

Because of the limited number of results for those parameters: 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 **March 6th, 2025**. Complaints received after this date will not be taken into consideration.

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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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 ≥ 3)
 BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)	24.228	1	-0.41	-0.32		
		24.229	1	-0.80	-0.74		
Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)	24.228	1	-0.41	-0.40	-0.87	
		24.229	1	-0.80	-0.88	-1.20	
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	24.228	1	-0.41	0.05	-0.13	
		24.229	1	-0.80	-0.50	-0.48	

Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 24.228
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 20 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-April-2027
Homogeneity 2.0 % **Homogeneity Parameter** FVIII inhibitor
 For any method used for the measurement of this parameter with a CV ≤ 6.7% 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 344
Number of Responders 323 **Response Rate** 94 %
Comments The following participants reported deviating results which were excluded from the statistical analysis:
215: 0.138 BU/mL
137: 0 BU/mL
1278: 88 BU/mL
3815: 61.9 BU/mL
3855: 89 BU/mL
9907186: 50.9 BU/mL

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.

Classification Overview	No classification	Negative	Equivocal	Positive
Total	3	0	0	351

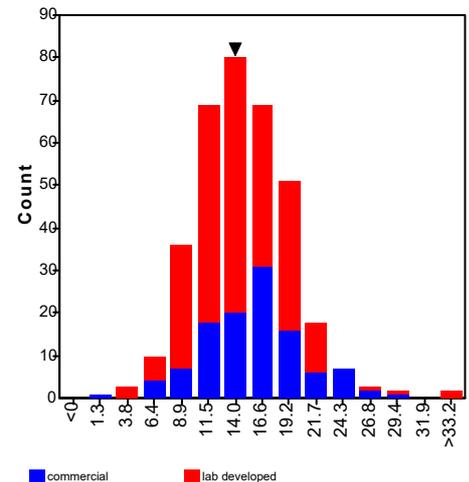
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	351	14.7	0.28	29.1	1.7 - 39.3	12.9	-0.41				
Lab-developed test	238	14.3	0.34	29.5	4.0 - 39.3	12.9	-0.32				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	351	14.7	0.28	29.1	1.7 - 39.3
Commercial Test	113	15.6	0.52	28.4	1.7 - 29.9
Other	58	14.8	0.82	33.9	1.7 - 29.9
Precision Biologics	24	14.4	0.89	24.1	9.3 - 25.6
Technoclone	31	17.7	0.80	20.2	8.8 - 24.4
Lab-developed test	238	14.3	0.34	29.5	4.0 - 39.3



Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No	24.229		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-April-2027		
Homogeneity	0.0 %	Homogeneity Parameter	FVIII inhibitor
Number of Participants	344	Response Rate	94 %
Number of Responders	323		
Comments	The following participants reported deviating results which were excluded from the statistical analysis: 215: 0.055 BU/mL 1278: 40 BU/mL 3815: 15.7 BU/mL		

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.

Classification Overview	No classification	Negative	Equivocal	Positive
Total	3	0	1	352

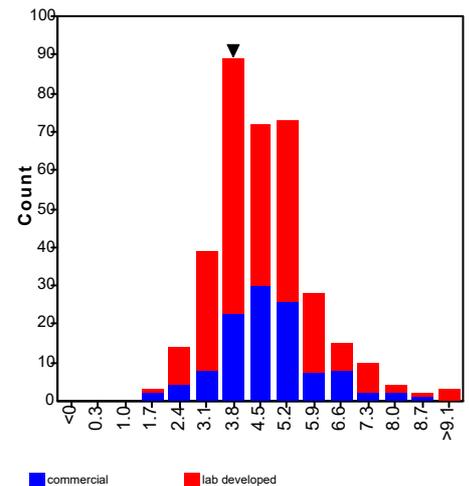
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	353	4.5	0.08	25.4	1.4 - 12.0	3.6	-0.80				
Lab-developed test	239	4.5	0.09	26.1	1.4 - 12.0	3.6	-0.74				

Other Reagents

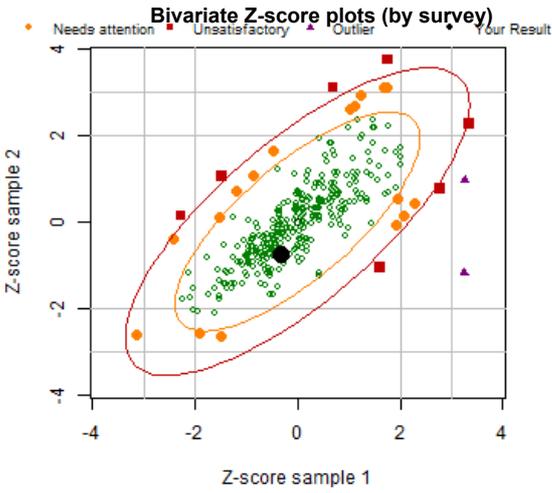
	n	assigned value	Uncert.	CV (%)	Range
Total Group	353	4.5	0.08	25.4	1.4 - 12.0
Commercial Test	114	4.6	0.13	23.4	1.8 - 8.7
Other	58	4.4	0.18	25.8	1.8 - 8.0
Precision Biologics	24	4.3	0.20	18.2	3.4 - 5.9
Technoclone	32	5.4	0.20	16.7	2.7 - 8.7
Lab-developed test	239	4.5	0.09	26.1	1.4 - 12.0



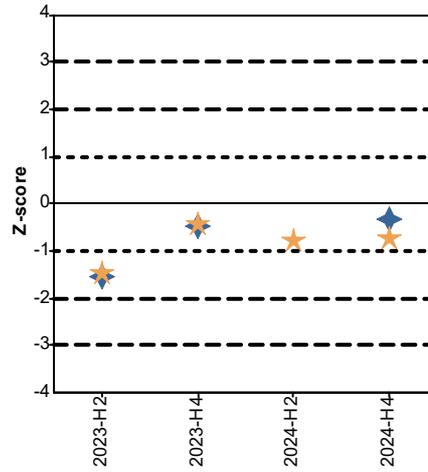
Factor VIII inhibitor

Factor VIII Inhibitor (by type of test)

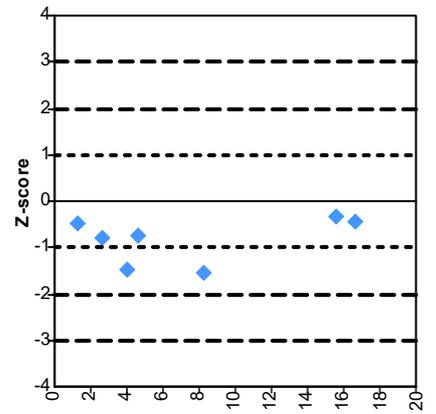
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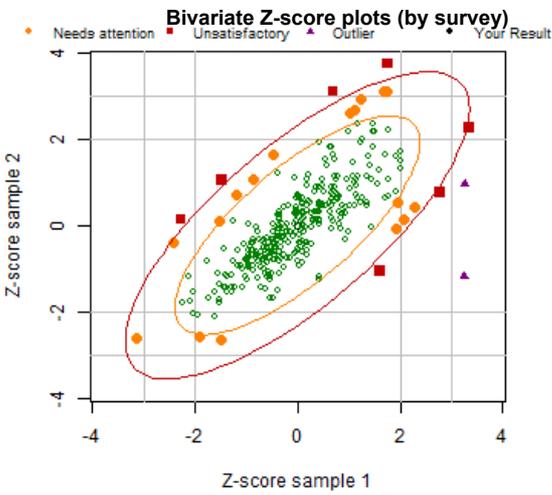
Z-score history (by survey)



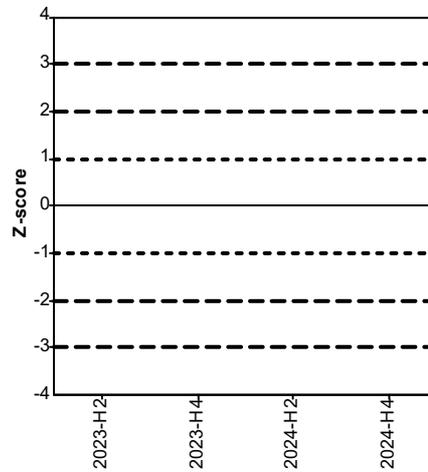
Z-score history (by consensus value)



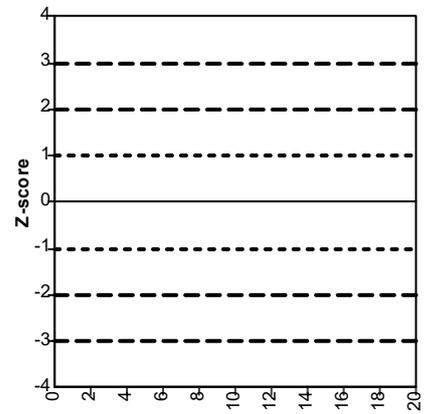
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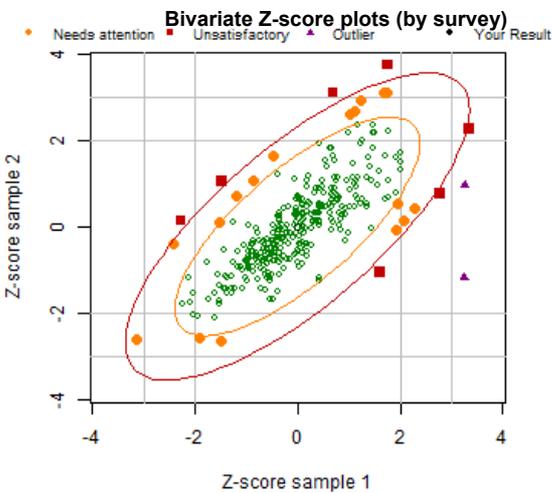
Z-score history (by survey)



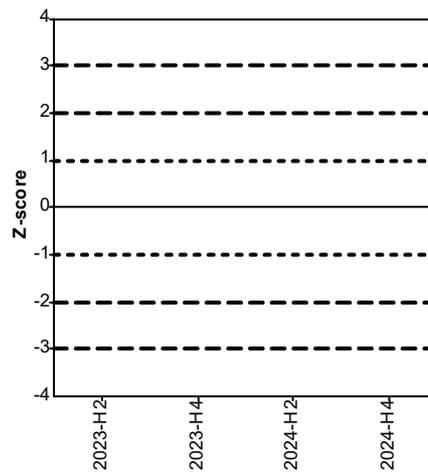
Z-score history (by consensus value)



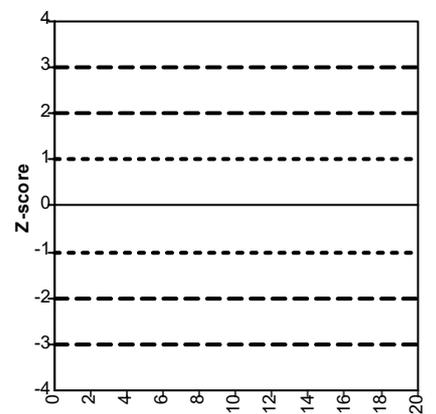
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)
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Sample No 24.228
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 20 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-April-2027
Homogeneity 2.0 % **Homogeneity Parameter** FVIII inhibitor
 For any method used for the measurement of this parameter with a **CV ≤ 6.7%** 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 344
Number of Responders 323 **Response Rate** 94 %

Comments The following participants reported deviating results which were excluded from the statistical analysis:
215: 0.138 BU/mL
137: 0 BU/mL
1278: 88 BU/mL
3815: 61.9 BU/mL
3855: 89 BU/mL
9907186: 50.9 BU/mL

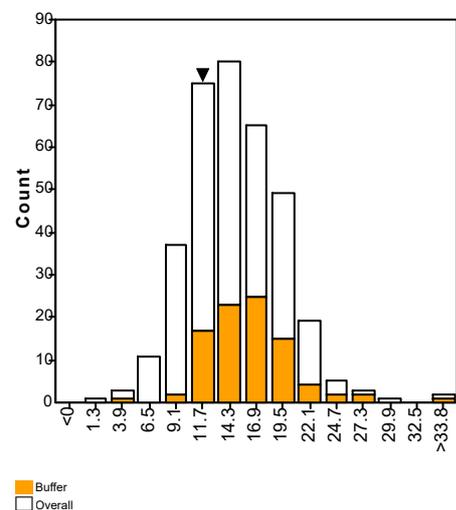
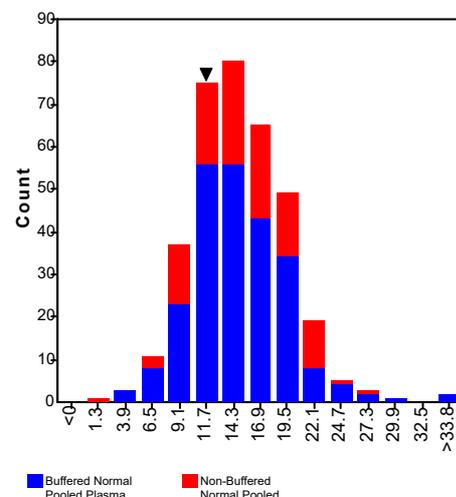
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	351	14.7	0.28	29.1	1.7 - 39.3	12.9	-0.41				
Buffered Normal Pooled Plasma	240	14.6	0.33	28.3	4.0 - 39.3	12.9	-0.40				
Buffer	92	15.9	0.45	21.9	4.0 - 33.8	12.9	-0.87				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	351	14.7	0.28	29.1	1.7 - 39.3
Non-Buffered Normal Pooled Plasma	111	14.9	0.56	31.5	1.7 - 28.0
Buffer	65	14.5	0.69	30.7	1.7 - 23.4
Buffer + Albumin	3	18.6			13.1 - 19.4
Factor VIII Deficient Plasma	24	14.4	1.13	30.9	5.7 - 22.7
Heat-activated normal plasma	4	17.9			13.7 - 24.0
Other	13	16.8	1.87	32.2	8.0 - 28.0
Unknown	2	13.7			8.4 - 19.0
Buffered Normal Pooled Plasma	240	14.6	0.33	28.3	4.0 - 39.3
Buffer + Albumin	26	15.2	0.98	26.3	9.3 - 39.3
Factor VIII Deficient Plasma	94	12.8	0.57	34.6	4.8 - 29.9
Heat-inactivated normal plasma	15	14.2	1.19	25.9	9.1 - 20.0
Other	13	15.4	1.42	26.5	10.5 - 24.7



Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)
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Sample No	24.229		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-April-2027		
Homogeneity	0.0 %	Homogeneity Parameter	FVIII inhibitor
Number of Participants	344	Response Rate	94 %
Number of Responders	323		
Comments	The following participants reported deviating results which were excluded from the statistical analysis: 215: 0.055 BU/mL 1278: 40 BU/mL 3815: 15.7 BU/mL		

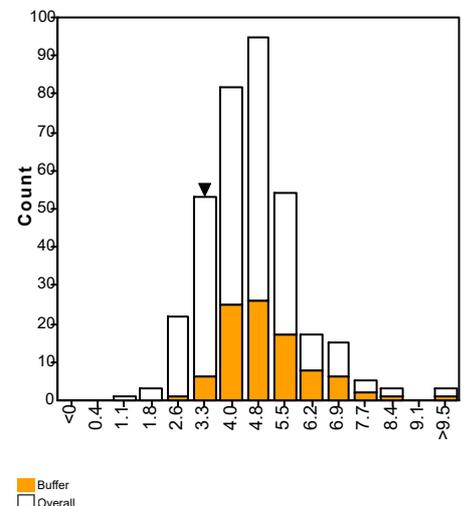
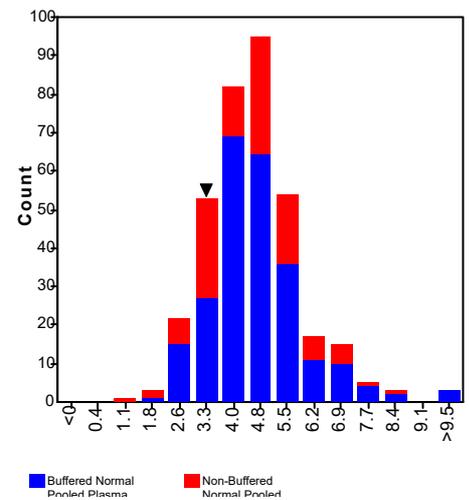
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Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	353	4.5	0.08	25.4	1.4 - 12.0	3.6	-0.80				
Buffered Normal Pooled Plasma	242	4.6	0.09	23.8	2.1 - 12.0	3.6	-0.88				
Buffer	93	4.9	0.14	22.2	2.5 - 11.4	3.6	-1.20				

Other Reagents

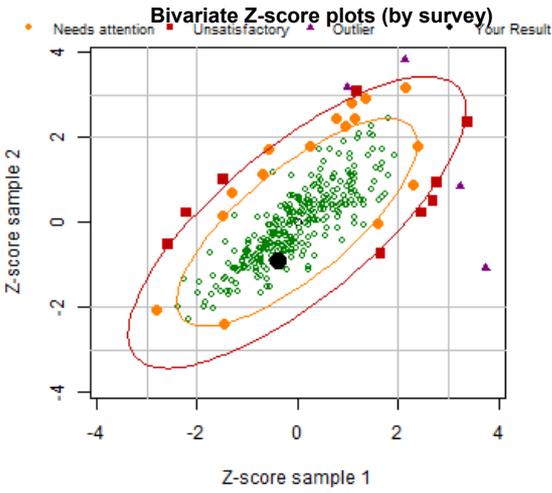
	n	assigned value	Uncert.	CV (%)	Range
Total Group	353	4.5	0.08	25.4	1.4 - 12.0
Non-Buffered Normal Pooled Plasma	111	4.4	0.15	28.5	1.4 - 8.1
Buffer	65	4.3	0.19	28.5	1.4 - 7.0
Buffer + Albumin	3	5.1			3.7 - 7.5
Factor VIII Deficient Plasma	24	4.3	0.31	27.8	2.7 - 8.1
Heat-activated normal plasma	4	5.8			4.1 - 6.4
Other	13	4.9	0.42	24.6	3.3 - 6.6
Unknown	2	3.7			2.4 - 5.0
Buffered Normal Pooled Plasma	242	4.6	0.09	23.8	2.1 - 12.0
Buffer + Albumin	27	4.7	0.24	21.5	3.4 - 12.0
Factor VIII Deficient Plasma	93	4.1	0.14	25.9	2.1 - 11.4
Heat-inactivated normal plasma	16	4.6	0.39	27.3	2.8 - 6.8
Other	13	4.7	0.29	18.1	3.3 - 6.7



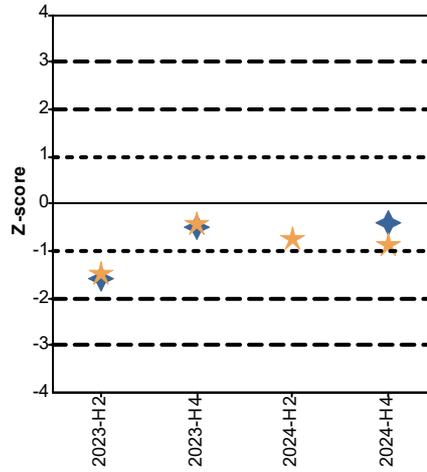
Factor VIII inhibitor

Factor VIII Inhibitor (by assay concept)

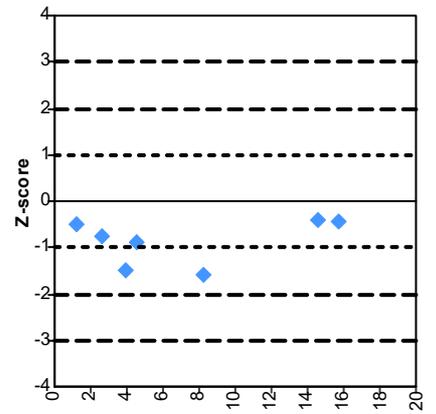
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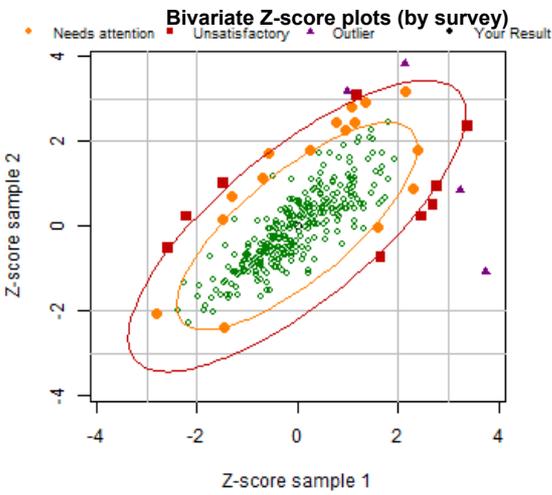
Z-score history (by survey)



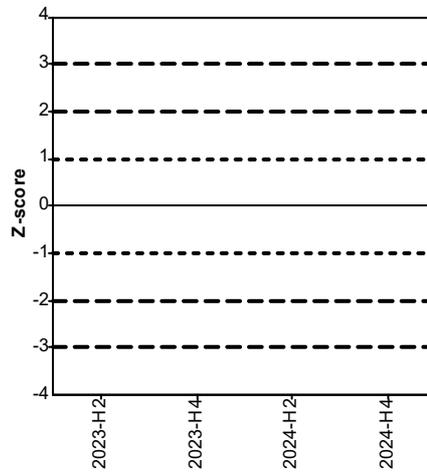
Z-score history (by consensus value)



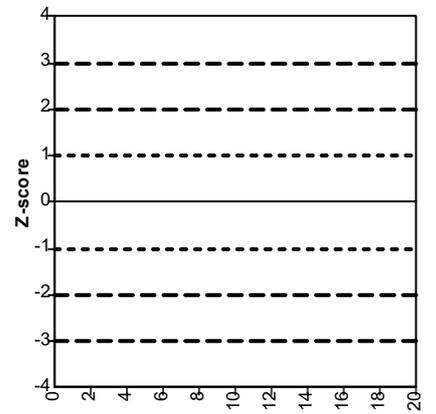
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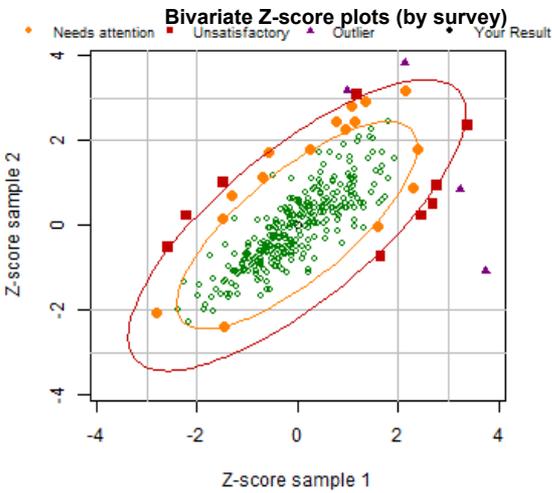
Z-score history (by survey)



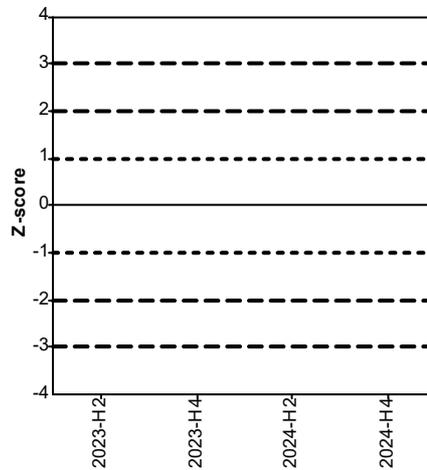
Z-score history (by consensus value)



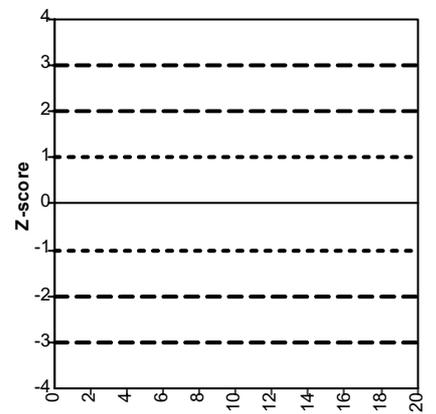
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No 24.228
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 20 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-April-2027
Homogeneity 2.0 % **Homogeneity Parameter** FVIII inhibitor
 For any method used for the measurement of this parameter with a CV ≤ 6.7% 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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Number of Responders 323 **Response Rate** 94 %
Comments The following participants reported deviating results which were excluded from the statistical analysis:
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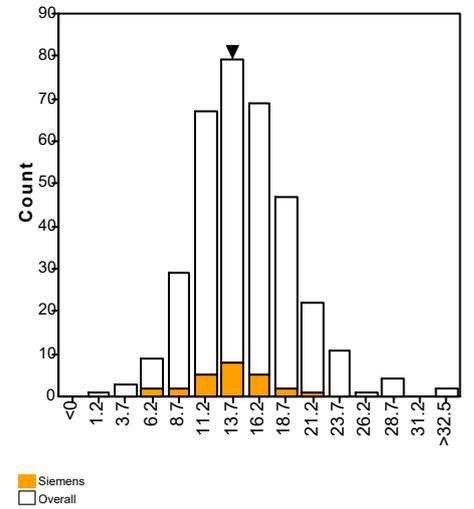
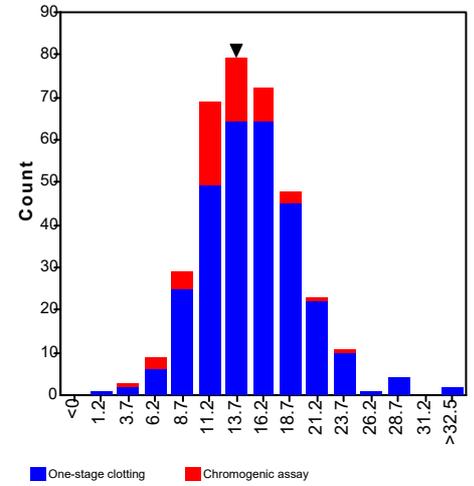
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Total Group	351	14.7	0.28	29.1	1.7 - 39.3	12.9	-0.41				
Chromogenic assay	56	12.7	0.51	23.8	4.8 - 22.7	12.9	0.05				
Siemens Factor VIII	25	13.4	0.90	26.8	6.8 - 21.5	12.9	-0.13				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	351	14.7	0.28	29.1	1.7 - 39.3
One-stage clotting assay	295	15.0	0.32	29.0	1.7 - 39.3
Hemoliance Synthasil APTT	1	12.6			-
Hyphen Biomed Cephen	1	21.7			-
Other	2	12.1			7.9 - 16.2
Roche APTT	2	13.9			13.7 - 14.0
Siemens Actin FS	49	13.9	0.78	31.4	6.9 - 22.5
Siemens Actin FSL	11	13.8	1.76	33.9	8.0 - 20.0
Siemens Pathromtin SL	28	15.1	1.00	27.9	9.5 - 23.3
Stago Cephalin/Kaolin/CK Prest	49	14.3	0.60	23.4	5.7 - 33.8
Stago PTT (automate)	13	14.7	1.54	30.2	7.1 - 25.6
Tcoag Automated APTT	1	13.0			-
Tcoag TriniClot APTT S	1	10.3			-
Tcoag TriniClot APTT-HS	2	13.6			10.2 - 17.0
Technoclone Dapttin	1	17.4			-
Technoclone Siron LS	1	19.2			-
Werfen HemosIL APTT lyophilised silica	1	17.0			-
Werfen HemosIL APTT-SP liquid silica	2	14.7			11.5 - 17.9
Werfen HemosIL SynthASil	124	15.9	0.52	29.0	1.7 - 39.3
Chromogenic assay	56	12.7	0.51	23.8	4.8 - 22.7
Chromogenix Coamatic Factor VIII	11	11.2	0.97	23.0	5.3 - 22.7
Chromogenix Coatest SP Factor VIII	3	11.0			4.8 - 11.7
Hyphen Biomed Biophen Factor VIII	2	14.4			9.9 - 18.9
Other	1	11.6			-
Precision Biologic Cryocheck Chromog	9	12.6			10.2 - 14.8
TCoag Trinichrom FVIII	2	16.4			16.0 - 16.8
Technoclone Factor VIII	1	13.5			-
Werfen Electrachrome FVIII	1	15.6			-



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No	24.229		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-April-2027		
Homogeneity	0.0 %	Homogeneity Parameter	FVIII inhibitor
Number of Participants	344	Response Rate	94 %
Number of Responders	323		
Comments	The following participants reported deviating results which were excluded from the statistical analysis: 215: 0.055 BU/mL 1278: 40 BU/mL 3815: 15.7 BU/mL		

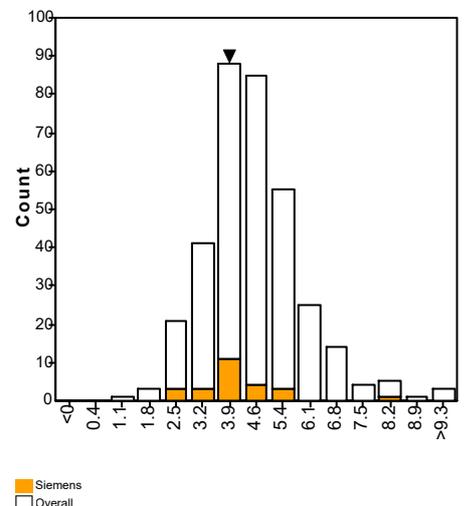
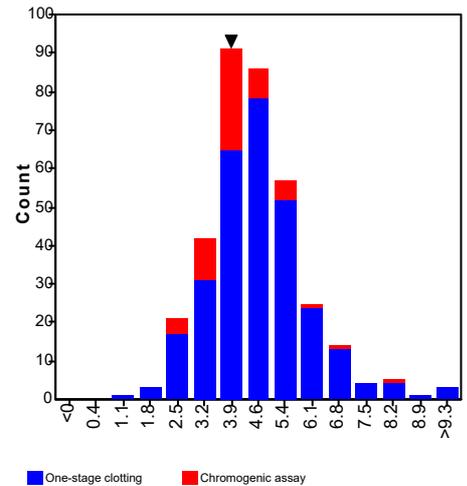
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Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	353	4.5	0.08	25.4	1.4 - 12.0	3.6	-0.80				
Chromogenic assay	57	4.0	0.13	19.4	2.5 - 8.0	3.6	-0.50				
Siemens Factor VIII	25	4.0	0.21	21.4	2.5 - 8.0	3.6	-0.48				

Other Reagents

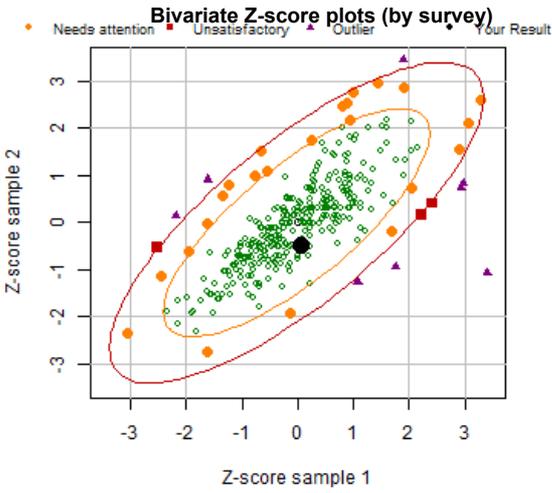
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One-stage clotting assay	296	4.6	0.09	25.5	1.4 - 12.0
Hemoliance Synthasil APTT	1	4.2			-
Hyphen Biomed Cephen	1	7.0			-
Other	2	3.8			2.9 - 4.6
Roche APTT	2	4.1			3.6 - 4.5
Siemens Actin FS	49	4.2	0.19	25.9	2.4 - 6.6
Siemens Actin FSL	11	4.7	0.42	24.1	1.4 - 7.6
Siemens Pathromtin SL	29	4.7	0.25	23.5	3.0 - 12.0
Stago Cephalin/Kaolin/CK Prest	49	4.4	0.17	21.6	2.1 - 11.4
Stago PTT (automate)	13	4.2	0.41	28.3	1.9 - 7.9
Tcoag Automated APTT	1	4.5			-
Tcoag TriniClot APTT S	1	3.8			-
Tcoag TriniClot APTT-HS	2	4.2			3.6 - 4.7
Technoclone Dapttin	1	5.2			-
Technoclone Siron LS	1	5.0			-
Werfen HemosIL APTT lyophilised silica	1	5.0			-
Werfen HemosIL APTT-SP liquid silica	2	4.3			3.5 - 5.0
Werfen HemosIL SynthASil	124	5.0	0.15	26.4	1.8 - 11.4
Chromogenic assay	57	4.0	0.13	19.4	2.5 - 8.0
Chromogenix Coamatic Factor VIII	11	3.9	0.20	13.9	3.1 - 6.0
Chromogenix Coatest SP Factor VIII	2	3.7			3.5 - 3.9
Hyphen Biomed Biophen Factor VIII	2	4.5			3.4 - 5.7
Other	1	3.2			-
Precision Biologic Cryocheck Chromog	9	3.9			3.4 - 4.9
TCoag Trinichrom FVIII	2	3.6			3.0 - 4.2
Technoclone Factor VIII	1	4.5			-
Werfen Electrachrome FVIII	3	5.4			2.5 - 6.8



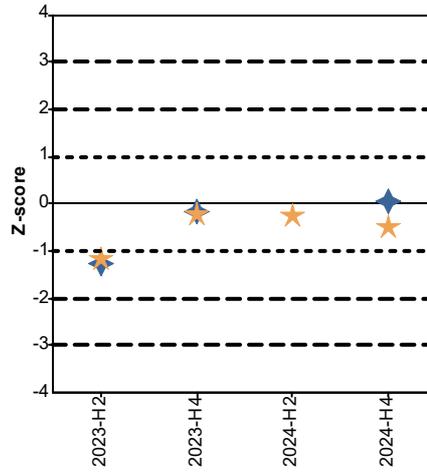
Factor VIII inhibitor

Factor VIII Inhibitor (by FVIII assay)

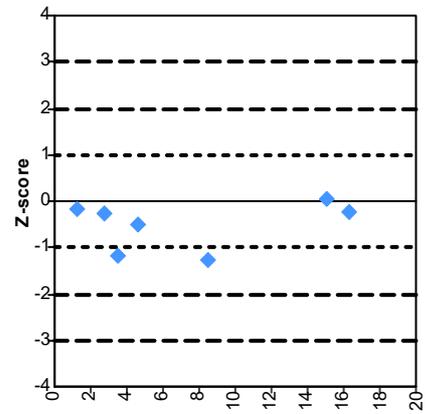
Instrument ID



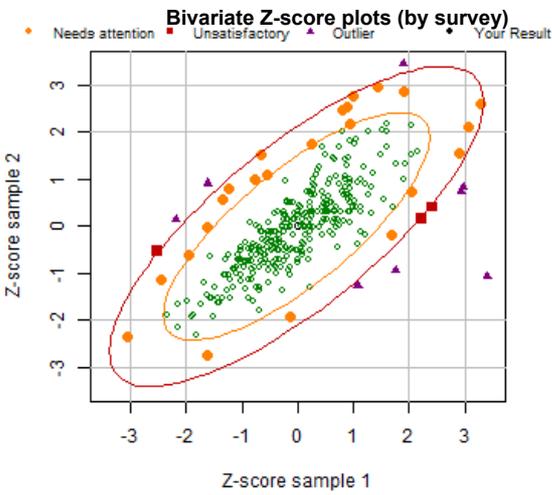
Z-score history (by survey)



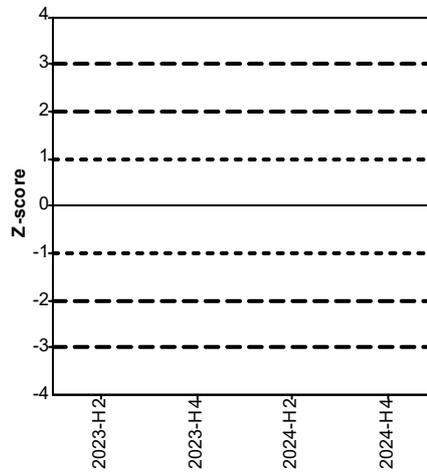
Z-score history (by consensus value)



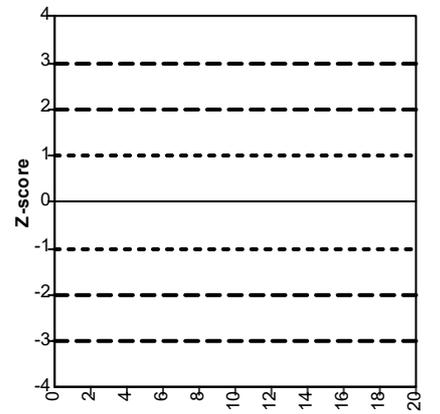
Instrument ID



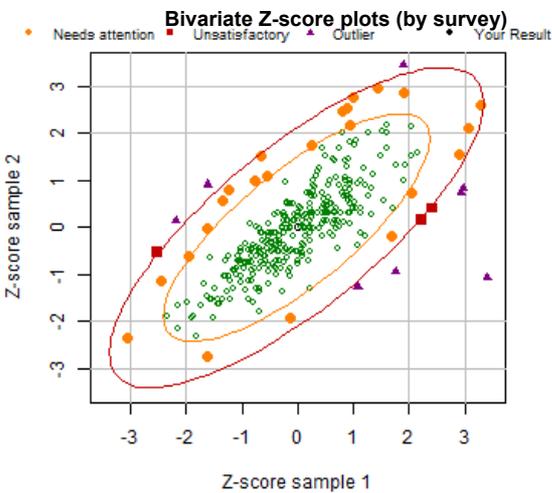
Z-score history (by survey)



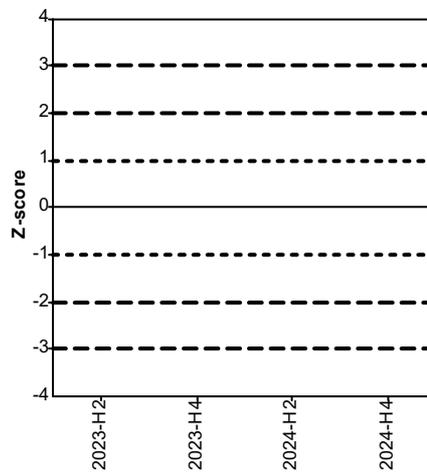
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

