

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-H4
Haemophilia
Labcode 1492

Date of Issue : 19-January-2026

Survey : 2025-H4

Report : Haemophilia

Note:

In the Survey Manual 2025 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2025 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

Participants have the option to submit three results per parameter for up to three different instruments and /or different methods. However, some participants submitted identical results three times, implying these were separate results. This is not the case and may affect the statistical analysis. The results submitted for the second and third system have been excluded from the statistical analysis. Please submit results no more than once unless they are a different measurement.

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 10th, 2026**. Complaints received after this date will not be taken into consideration.

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

Note: The current Survey Manual can be downloaded from the 'Participant Area' of the ECAT website. Login and select the option 'View Documents'.

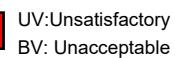
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OVERVIEW Z-SCORES

 UV:Satisfactory (-2 ≤ Z-score ≤ 2)
 UV: Need attention (-3 < Z-score < -2 or 2 < Z-score < 3)
 UV:Unsatisfactory (Z-score ≤ -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)	25.234	1	-1.22	-1.25	-1.20	-1.17	
		25.235	1					
Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)	25.234	1	-1.22	0.03	-1.20	-0.39	
		25.235	1					
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	25.234	1	-1.22	-1.36	-1.36	-1.42	
		25.235	1					

Factor VIII inhibitor
Factor VIII Inhibitor (by type of test)

Sample No	25.234
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 1 BU/mL
Prior Use	None
Unit	BU/mL
Expiry Date	30-September-2028
Homogeneity	6.4 %
	Homogeneity Parameter
	FVIII inhibitor
	For any method used for the measurement of this parameter with a CV \leq 21.3% 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	348
Number of Responders	323
Comments	None.

Classification Overview	No classification	Negative	Equivocal	Positive
Total	3	27	19	323

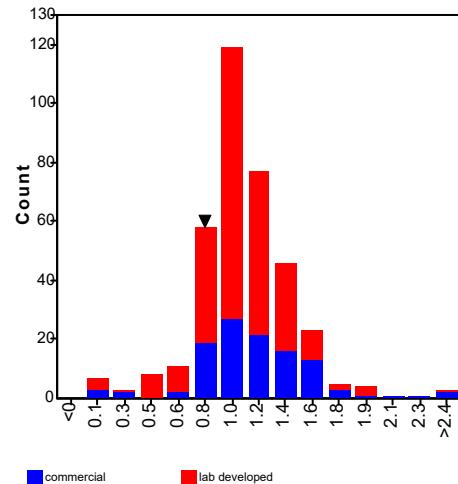
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	366	1.1	0.02	22.5	0.0 - 7.7	0.8	-1.22				
Lab-developed test	254	1.1	0.02	20.8	0.0 - 6.4	0.8	-1.25				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	366	1.1	0.02	22.5	0.0 - 7.7
Commercial Test	112	1.2	0.04	26.4	0.0 - 7.7
Other	53	1.1	0.05	25.6	0.0 - 2.6
Precision Biologics	25	1.0	0.05	21.8	0.3 - 1.7
Technoclone	34	1.3	0.05	16.1	0.9 - 7.7
Lab-developed test	254	1.1	0.02	20.8	0.0 - 6.4



Factor VIII inhibitor
Factor VIII Inhibitor (by type of test)

Sample No	25.235			
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 9 BU/mL			
Prior Use	None			
Unit	BU/mL			
Expiry Date	30-September-2028			
Homogeneity	4.5 %	Homogeneity Parameter		FVIII inhibitor
	For any method used for the measurement of this parameter with a CV ≤ 15.0% 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	348			
Number of Responders	323	Response Rate		93 %
Comments	The following participant reported a deviating result which was excluded from the statistical analysis: 6222: 128 BU/mL			

Classification Overview	No classification	Negative	Equivocal	Positive
Total	1	2	2	367

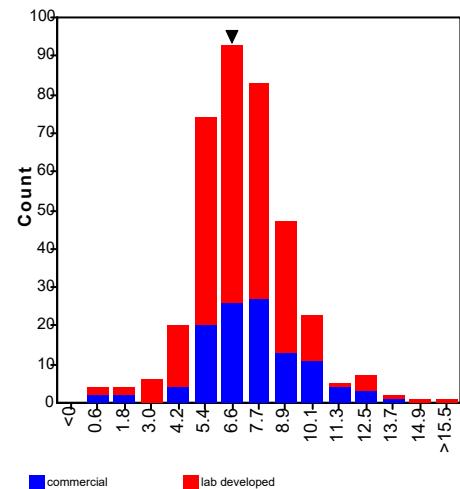
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	370	7.1	0.12	26.1	0.0 - 17.4	7.0	-0.04				
Lab-developed test	257	6.9	0.14	25.8	0.0 - 17.4	7.0	0.03				

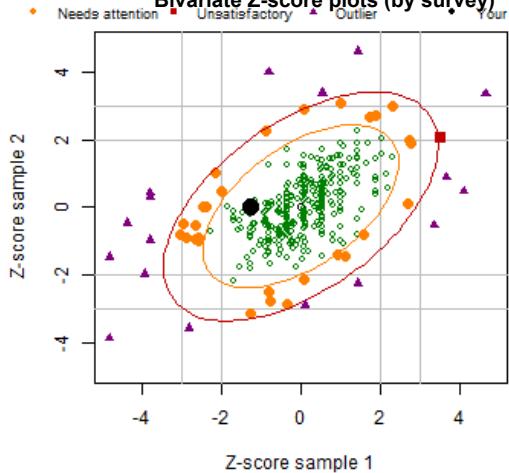
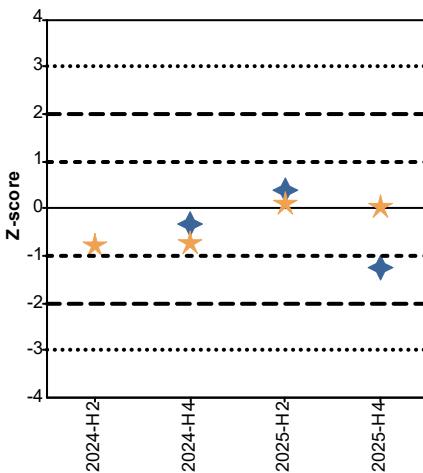
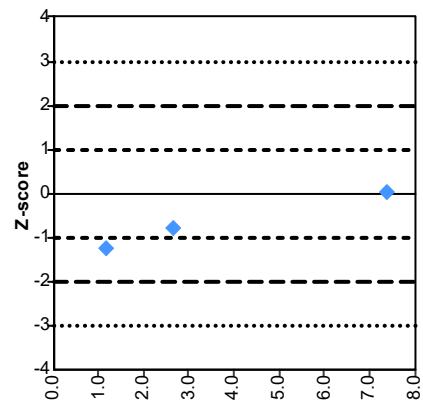
Other Reagents

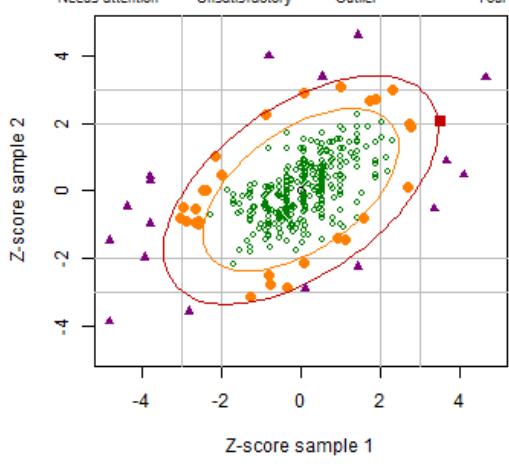
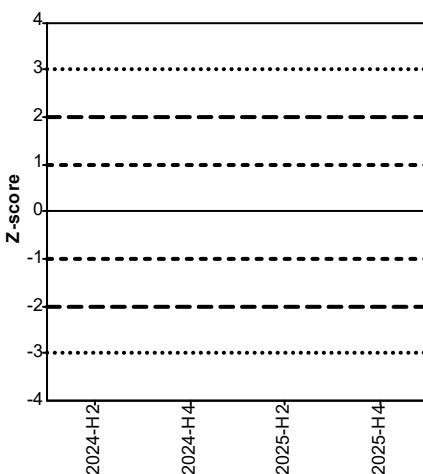
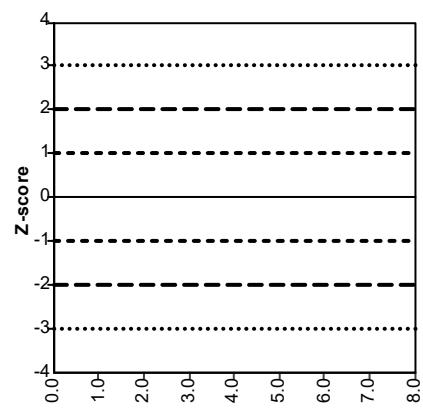
	n	assigned value	Uncert.	CV (%)	Range
Total Group	370	7.1	0.12	26.1	0.0 - 17.4
Commercial Test	113	7.4	0.24	27.6	0.1 - 14.2
Other	54	7.1	0.37	30.9	0.1 - 14.2
Precision Biologics	25	6.5	0.28	17.6	1.5 - 10.3
Technoclone	34	8.5	0.42	23.0	5.2 - 12.0
Lab-developed test	257	6.9	0.14	25.8	0.0 - 17.4

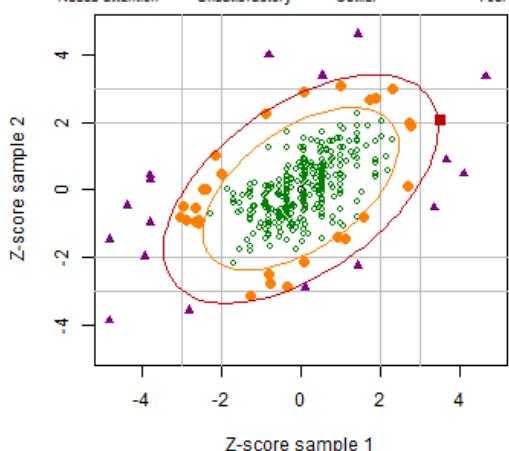
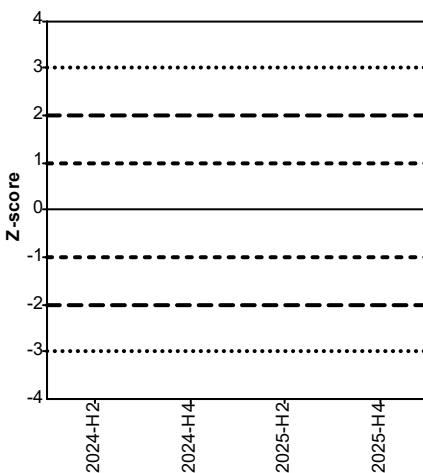
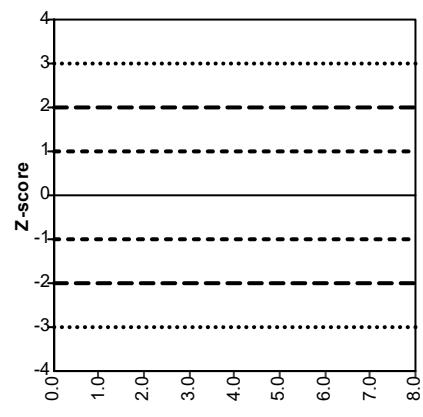


Factor VIII inhibitor
Factor VIII Inhibitor (by type of test)

 Instrument ID

 • Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result

Z-score history (by survey)

Z-score history (by consensus value)

 Instrument ID

 • Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result

Z-score history (by survey)

Z-score history (by consensus value)

 Instrument ID

 • Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result

Z-score history (by survey)

Z-score history (by consensus value)


Factor VIII inhibitor
Factor VIII Inhibitor (by assay concept)

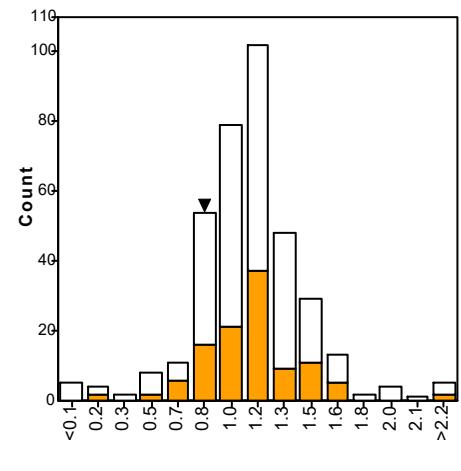
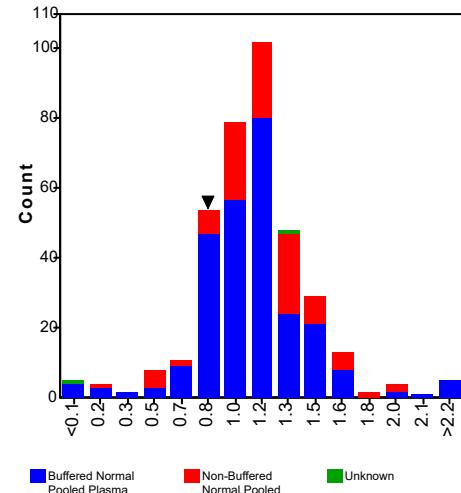
Sample No	25.234								
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 1 BU/mL								
Prior Use	None								
Unit	BU/mL								
Expiry Date	30-September-2028								
Homogeneity	6.4 %	Homogeneity Parameter		FVIII inhibitor					
		For any method used for the measurement of this parameter with a CV ≤ 21.3% 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	348								
Number of Responders	323	Response Rate		93 %					
Comments	None.								

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	366	1.1	0.02	22.5	0.0 - 7.7	0.8	-1.22				
Buffered Normal Pooled Plasma	265	1.1	0.02	21.9	0.0 - 7.7	0.8	-1.20				
Buffer	111	1.1	0.03	23.4	0.1 - 2.6	0.8	-1.17				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	366	1.1	0.02	22.5	0.0 - 7.7
Non-Buffered Normal Pooled Plasma	99	1.2	0.03	22.3	0.1 - 2.0
Buffer	55	1.2	0.04	19.1	0.1 - 1.9
Buffer + Albumin	2	1.2			1.1 - 1.4
Factor VIII Deficient Plasma	24	1.2	0.07	24.3	0.6 - 2.0
Heat-activated normal plasma	2	1.6			1.5 - 1.7
Other	15	0.9	0.10	33.7	0.4 - 1.3
Unknown	1	1.0			-
Buffered Normal Pooled Plasma	265	1.1	0.02	21.9	0.0 - 7.7
Buffer + Albumin	27	1.1	0.06	23.1	0.0 - 1.5
Factor VIII Deficient Plasma	99	1.1	0.03	19.1	0.0 - 7.7
Heat-inactivated normal plasma	12	1.2	0.15	34.2	0.8 - 2.0
Other	15	1.1	0.11	31.4	0.0 - 1.6
Unknown	1	1.1			-
Unknown	2	0.7			0.0 - 1.4
Buffer	1	1.4			-
Unknown	1	0.0			-



Factor VIII inhibitor
Factor VIII Inhibitor (by assay concept)

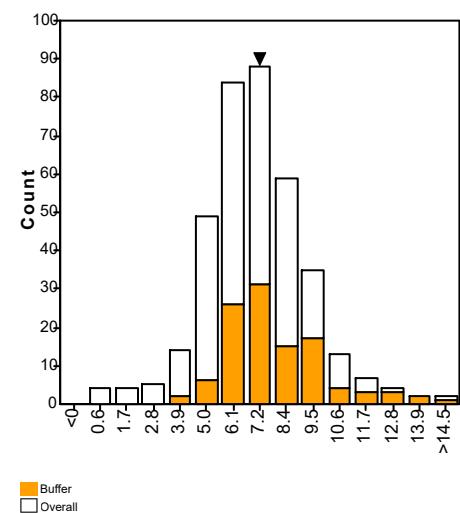
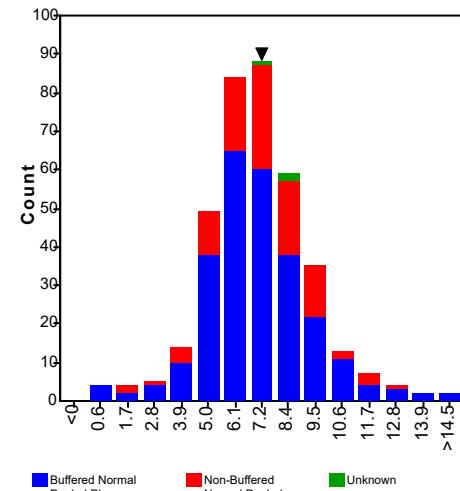
Sample No	25.235		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 9 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-September-2028		
Homogeneity	4.5 %	Homogeneity Parameter	FVIII inhibitor
	For any method used for the measurement of this parameter with a CV \leq 15.0% the criterion 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	348		
Number of Responders	323	Response Rate	93 %
Comments	The following participant reported a deviating result which was excluded from the statistical analysis: 6222: 128 BU/mL		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	370	7.1	0.12	26.1	0.0 - 17.4	7.0	-0.04				
Buffered Normal Pooled Plasma	265	7.0	0.14	26.7	0.0 - 17.4	7.0	0.02				
Buffer	110	7.7	0.21	23.2	3.4 - 15.2	7.0	-0.39				

Other Reagents

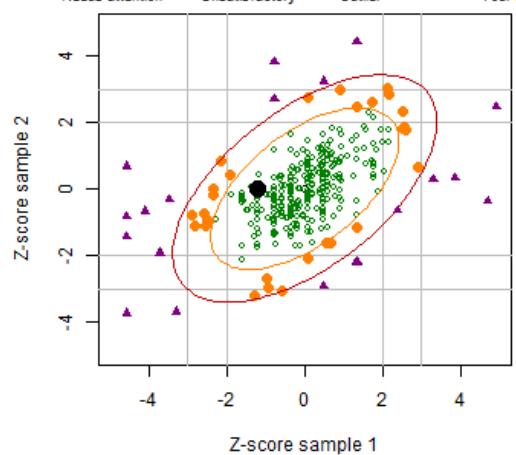
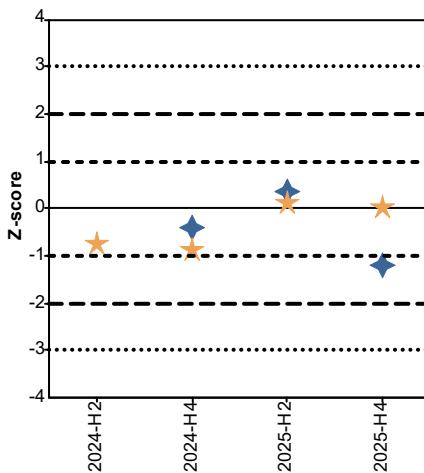
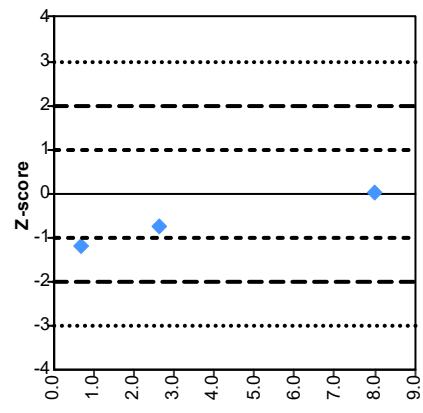
	n	assigned value	Uncert.	CV (%)	Range
Total Group	370	7.1	0.12	26.1	0.0 - 17.4
Non-Buffered Normal Pooled Plasma	102	7.3	0.22	24.7	1.8 - 12.8
Buffer	56	7.5	0.28	22.3	4.2 - 12.0
Buffer + Albumin	2	7.6			6.4 - 8.7
Factor VIII Deficient Plasma	25	7.1	0.50	28.4	4.4 - 11.5
Heat-activated normal plasma	2	9.0			5.2 - 12.8
Other	16	6.4	0.78	38.8	1.8 - 9.0
Unknown	1	8.0			-
Buffered Normal Pooled Plasma	265	7.0	0.14	26.7	0.0 - 17.4
Buffer + Albumin	27	6.8	0.49	30.2	0.0 - 10.4
Factor VIII Deficient Plasma	101	6.2	0.21	27.0	0.8 - 17.4
Heat-inactivated normal plasma	11	6.4	0.44	18.4	3.7 - 7.9
Other	15	7.7	0.60	24.3	0.1 - 10.3
Unknown	1	8.0			-
Unknown	3	8.0			6.9 - 8.1
Buffer	2	7.5			6.9 - 8.1
Unknown	1	8.0			-



Factor VIII inhibitor
Factor VIII Inhibitor (by assay concept)

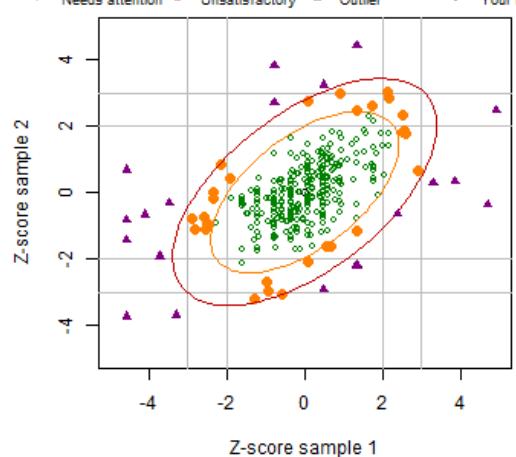
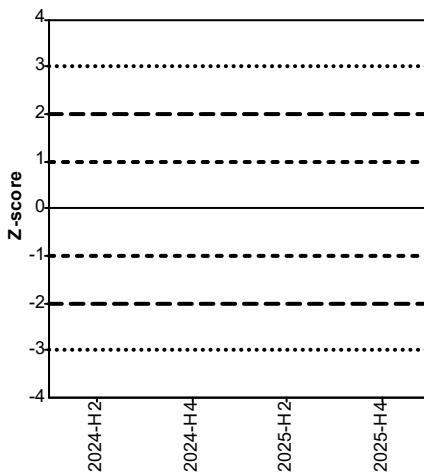
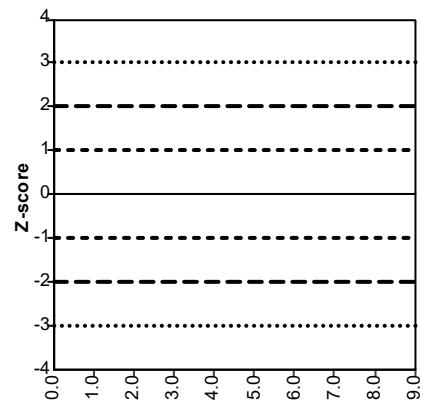
Instrument ID	
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• Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result


Z-score history (by survey)

Z-score history (by consensus value)


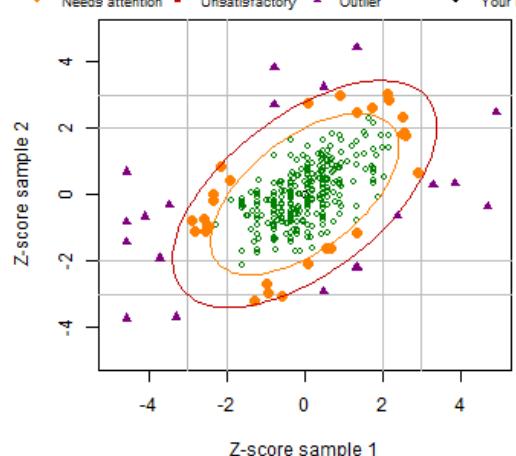
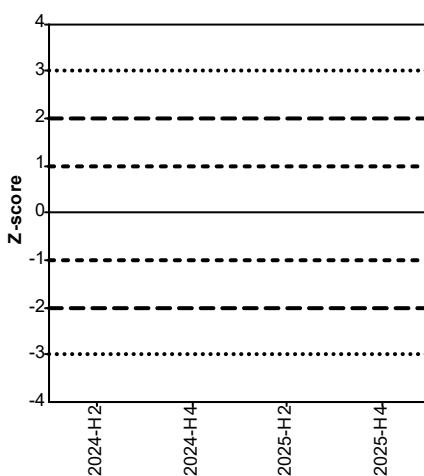
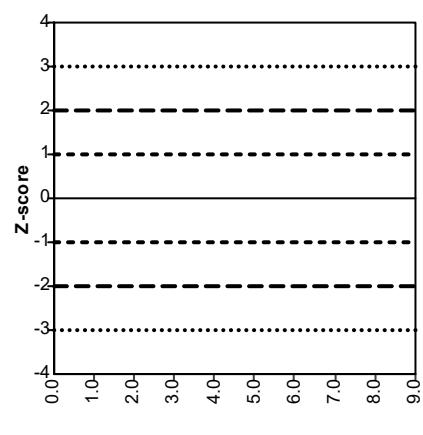
Instrument ID	
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• Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result


Z-score history (by survey)

Z-score history (by consensus value)


Instrument ID	
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• Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result


Z-score history (by survey)

Z-score history (by consensus value)


Factor VIII inhibitor
Factor VIII Inhibitor (by FVIII assay)

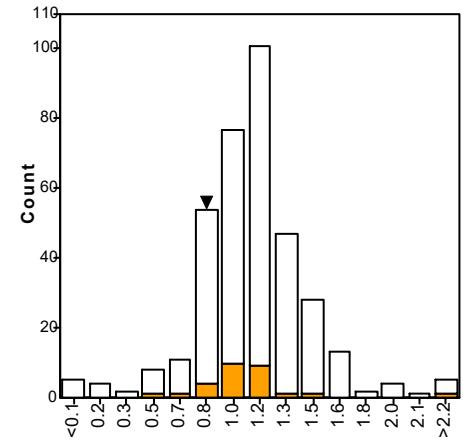
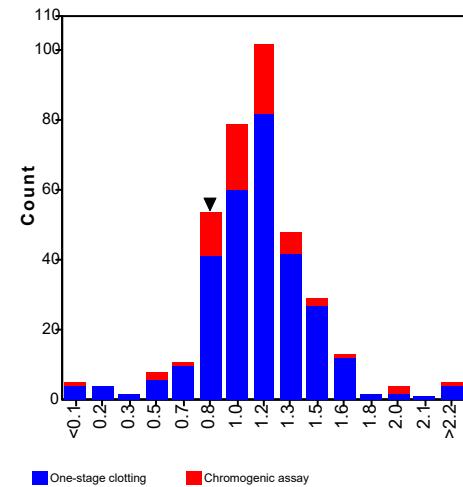
Sample No	25.234		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 1 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	30-September-2028		
Homogeneity	6.4 %	Homogeneity Parameter	FVIII inhibitor
		For any method used for the measurement of this parameter with a CV \leq 21.3% the criterion 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	348		
Number of Responders	323	Response Rate	93 %
Comments	None.		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	366	1.1	0.02	22.5	0.0 - 7.7	0.8	-1.22				
Chromogenic assay	68	1.1	0.03	18.1	0.0 - 7.7	0.8	-1.36				
Siemens Factor VIII	28	1.0	0.04	16.0	0.4 - 7.7	0.8	-1.42				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	366	1.1	0.02	22.5	0.0 - 7.7
One-stage clotting assay	298	1.1	0.02	23.4	0.0 - 6.4
Hemoliance Synthasil APTT	2	1.1			0.9 - 1.3
Hyphen Biomed Cephen	2	1.1			0.9 - 1.3
Roche APTT	2	1.1			1.0 - 1.2
Siemens Actin FS	52	1.1	0.04	21.6	0.5 - 1.7
Siemens Actin FSL	12	1.1	0.07	16.8	0.8 - 1.6
Siemens Pathromtin SL	30	1.1	0.08	32.1	0.0 - 2.3
Stago Cephalin/Kaolin/CK Prest	52	1.1	0.04	21.6	0.4 - 2.6
Stago PTT (automate)	13	1.1	0.07	18.3	0.8 - 1.5
Tcoag TriniClot APTT S	2	1.0			0.8 - 1.2
Tcoag TriniClot APTT-HS	1	1.0			-
Technoclone Daptin	2	1.2			0.9 - 1.5
Werfen HemosIL APTT-SP liquid silica	1	1.0			-
Werfen HemosIL SynthASil	122	1.1	0.03	26.0	0.0 - 6.4
Chromogenic assay	68	1.1	0.03	18.1	0.0 - 7.7
Chromogenix Coamatic Factor VIII	14	1.2	0.08	19.5	0.8 - 1.9
Chromogenix Coatest SP Factor VIII	3	0.9			0.5 - 0.9
Hyphen Biomed Biophen Factor VIII	2	1.1			1.1 - 1.2
Other	3	0.9			0.0 - 1.0
Precision Biologic Cryocheck Chromog	9	1.0			0.8 - 1.2
TCoag Trinichrom FVIII	1	1.1			-
Technoclone Factor VIII	3	1.2			1.0 - 1.3
Werfen Electrachrome FVIII	5	1.1			1.0 - 2.0



Factor VIII inhibitor
Factor VIII Inhibitor (by FVIII assay)

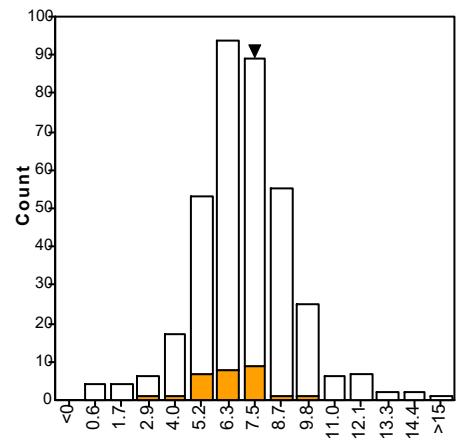
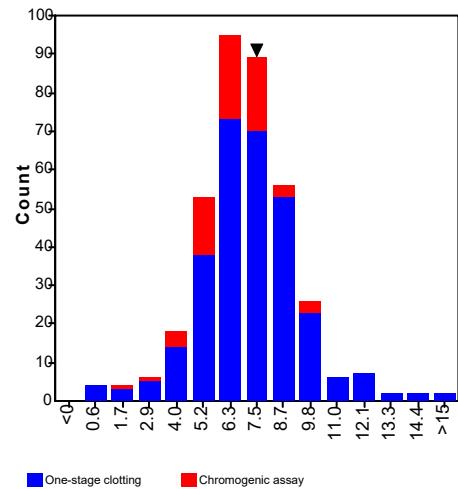
Sample No	25.235								
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 9 BU/mL								
Prior Use	None								
Unit	BU/mL								
Expiry Date	30-September-2028								
Homogeneity	4.5 %	Homogeneity Parameter		FVIII inhibitor					
		For any method used for the measurement of this parameter with a CV \leq 15.0% 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	348								
Number of Responders	323	Response Rate		93 %					
Comments	The following participant reported a deviating result which was excluded from the statistical analysis: 6222: 128 BU/mL								

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	370	7.1	0.12	26.1	0.0 - 17.4	7.0	-0.04				
Chromogenic assay	68	6.4	0.20	21.0	1.5 - 10.3	7.0	0.43				
Siemens Factor VIII	28	6.4	0.31	20.6	3.0 - 10.3	7.0	0.43				

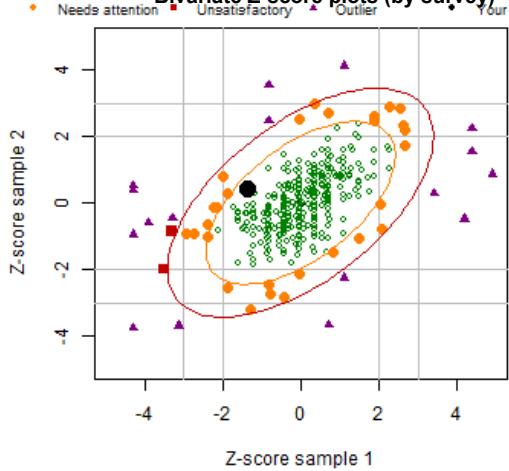
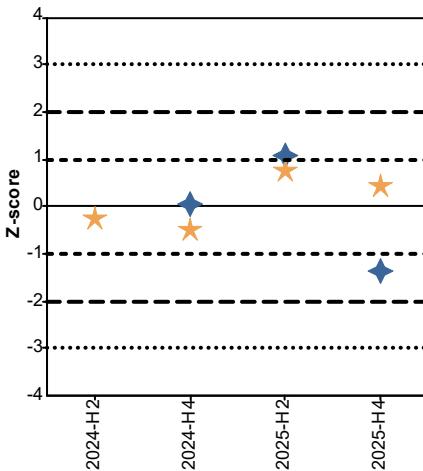
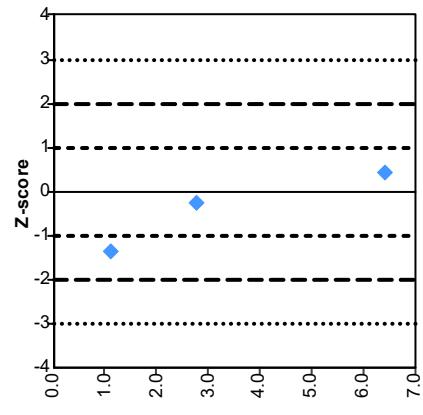
Other Reagents

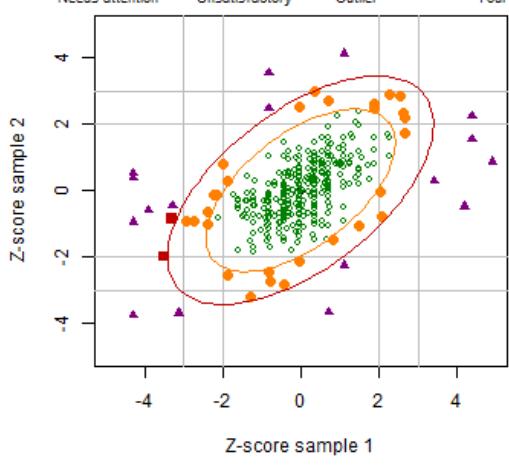
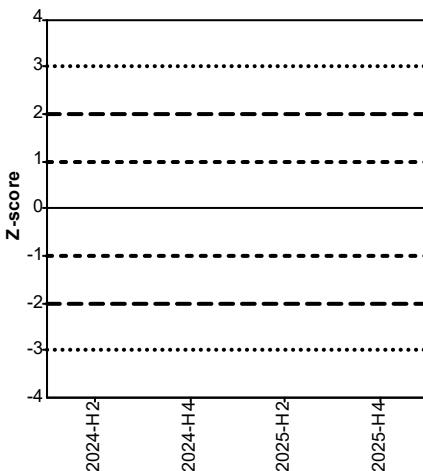
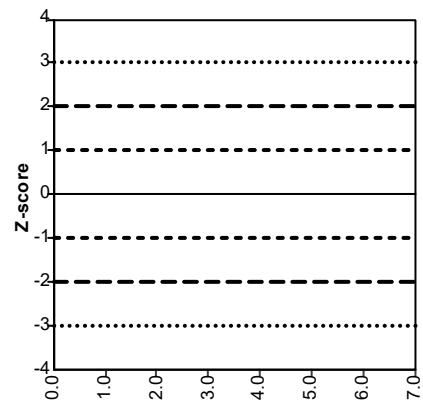
	n	assigned value	Uncert.	CV (%)	Range
Total Group	370	7.1	0.12	26.1	0.0 - 17.4
One-stage clotting assay	302	7.2	0.14	26.7	0.0 - 17.4
Hemoliance Synthasil APTT	2	8.7			7.1 - 10.4
Hyphen Biomed Cephen	2	6.7			5.8 - 7.7
Roche APTT	2	7.6			5.8 - 9.4
Siemens Actin FS	53	6.3	0.28	25.9	1.8 - 11.8
Siemens Actin FSL	13	6.9	0.67	28.1	2.0 - 9.6
Siemens Pathromtin SL	30	7.3	0.39	23.3	0.0 - 12.0
Stago Cephalin/Kaolin/CK Prest	53	7.2	0.28	22.5	3.8 - 14.2
Stago PTT (automate)	13	7.3	0.38	15.1	5.9 - 9.6
Tcoag TriniClot APTT S	2	5.7			5.5 - 5.8
Tcoag TriniClot APTT-HS	1	6.0			-
Technoclone Dapttin	2	7.8			7.6 - 8.0
Werfen HemosIL APTT-SP liquid silica	1	4.7			-
Werfen HemosIL SynthASil	123	7.7	0.25	28.6	0.1 - 17.4
Chromogenic assay	68	6.4	0.20	21.0	1.5 - 10.3
Chromogenix Coamatic Factor VIII	14	6.6	0.42	19.1	4.6 - 8.5
Chromogenix Coatest SP Factor VIII	3	5.2			4.6 - 6.0
Hyphen Biomed Biophen Factor VIII	2	6.5			6.4 - 6.5
Other	3	5.2			4.3 - 5.4
Precision Biologic Cryocheck Chromog	9	5.9			1.5 - 9.5
TCoag Trinichrom FVIII	1	6.3			-
Technoclone Factor VIII	3	7.6			5.8 - 8.4
Werfen Electrachrome FVIII	5	7.6			6.4 - 9.6

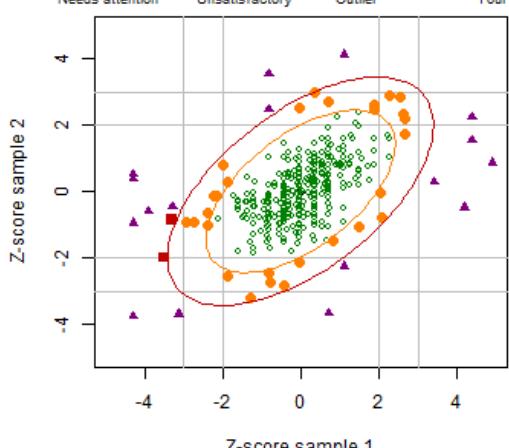
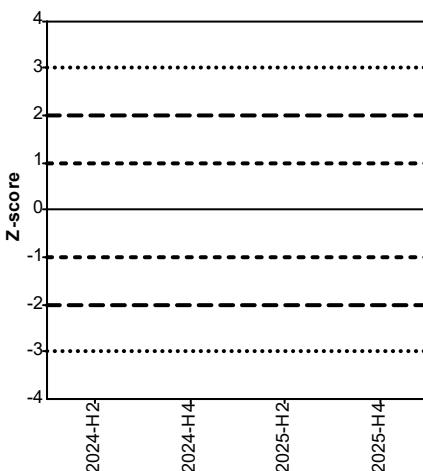

 Siemens
Overall

Factor VIII inhibitor
Factor VIII Inhibitor (by FVIII assay)

 Instrument ID

 • Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result

Z-score history (by survey)

Z-score history (by consensus value)

 Instrument ID

 • Needs attention ■ Unsatisfactory ▲ Outlier ● Your Result

Z-score history (by survey)

Z-score history (by consensus value)

 Instrument ID

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Z-score history (by survey)

Z-score history (by consensus value)
