

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-H2

Haemophilia

Labcode 1492

Date of Issue : 14-July-2025

Survey : 2025-H2

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

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.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before : **September 23rd, 2025.**

Complaints received after this date will not be taken into consideration.

This report is authorized by: Dr.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 ($-2 \leq \text{Z-score} \leq 2$)
  UV: Need attention ($-3 < \text{Z-score} < -2$ or $2 < \text{Z-score} < 3$)
  UV:Unsatisfactory ($\text{Z-score} \leq -3$ or ≥ 3)
  BV: Unacceptable

Module	Parameter	Sample	Test System	Total	Assay	Method	Bivariate Analysis
Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)	25.115	1	0.32	0.39		
		25.116	1	0.02	0.10		
Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)	25.115	1	0.32	0.36	0.06	
		25.116	1	0.02	0.11	-0.09	
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	25.115	1	0.32	1.08	1.35	
		25.116	1	0.02	0.75	0.86	

Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 25.115
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 25.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-January-2028
Homogeneity 3.9 %

Homogeneity Parameter Factor VIII Inhibitor

For any method used for the measurement of this parameter with a $CV \leq 13.0\%$ 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 343
Number of Responders 320
Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis :
102: 1.2 BU/mL
3606: 0.4 BU/mL
6222: 160 BU/mL
3855: 89 BU/mL

Participants **610** and **1180** reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25.115 and 25.116.

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	1	3	0	358

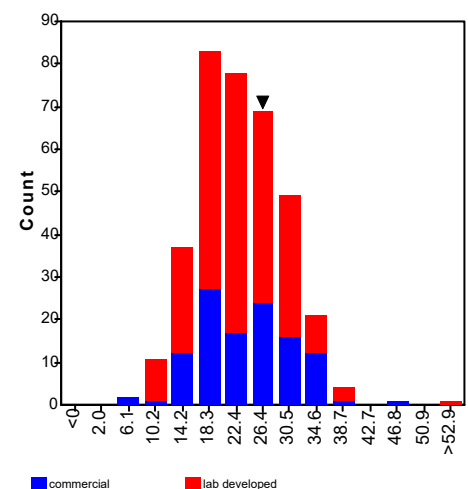
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	356	22.9	0.44	29.4	4.3 - 57.8	25.0	0.32				
Lab-developed test	243	22.5	0.52	28.6	9.0 - 57.8	25.0	0.39				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	356	22.9	0.44	29.4	4.3 - 57.8
Commercial Test	113	23.7	0.86	30.8	4.3 - 48.0
Other	59	21.7	1.22	34.5	4.3 - 48.0
Precision Biologics	22	22.2	1.45	24.5	14.0 - 35.6
Technoclone	32	28.1	1.14	18.4	17.0 - 35.3
Lab-developed test	243	22.5	0.52	28.6	9.0 - 57.8



Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 25.116
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-January-2028
Homogeneity 4.0 %

Homogeneity Parameter Factor VIII Inhibitor

For any method used for the measurement of this parameter with a $CV \leq 13.3\%$ 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 343

Number of Responders 320

Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis :

126: 52.5 BU/mL
1425: 38.40 BU/mL
3855: 38 BU/mL
3606: 0.0 BU/mL

Participants **610** and **1180** reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25.115 and 25.116.

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	1	4	4	351

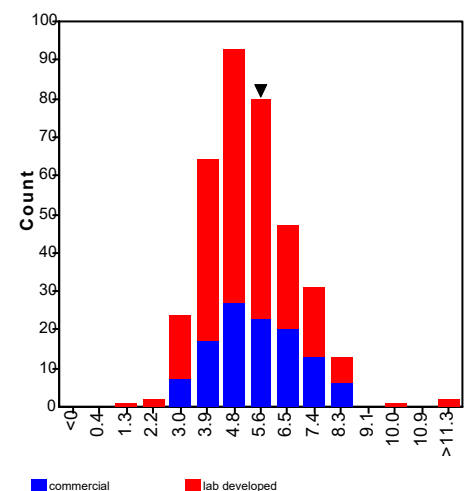
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	358	5.3	0.09	25.9	1.1 - 11.4	5.3	0.02				
Lab-developed test	245	5.2	0.10	25.4	1.1 - 11.4	5.3	0.10				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	358	5.3	0.09	25.9	1.1 - 11.4
Commercial Test	113	5.5	0.17	26.7	2.7 - 8.4
Other	58	5.1	0.23	28.2	2.7 - 8.4
Precision Biologics	23	5.0	0.26	19.8	3.4 - 6.6
Technoclone	32	6.5	0.23	15.9	3.8 - 8.2
Lab-developed test	245	5.2	0.10	25.4	1.1 - 11.4

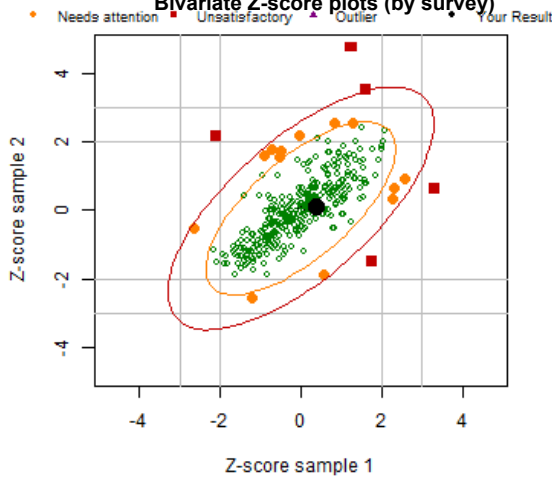


Factor VIII inhibitor

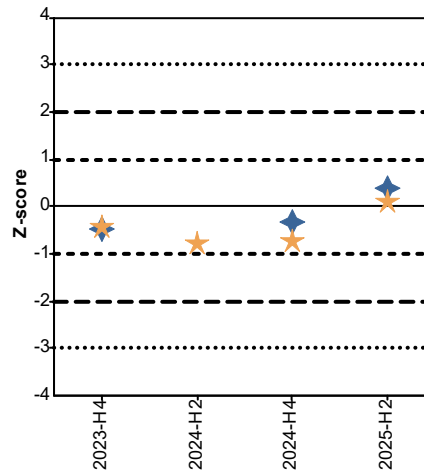
Factor VIII Inhibitor (by type of test)

Instrument ID

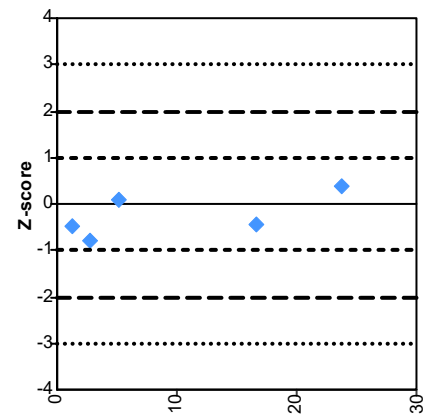
Bivariate Z-score plots (by survey)



Z-score history (by survey)

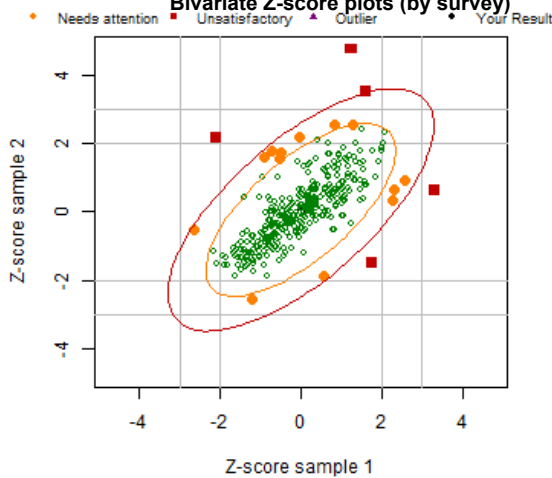


Z-score history (by consensus value)

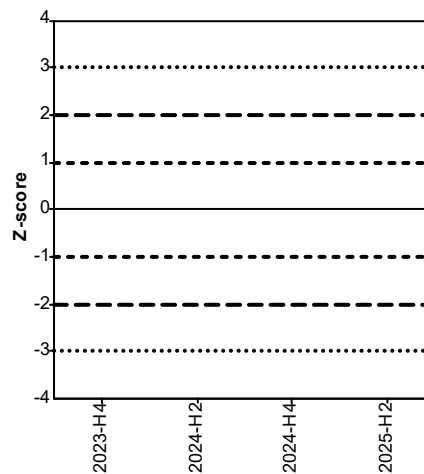


Instrument ID

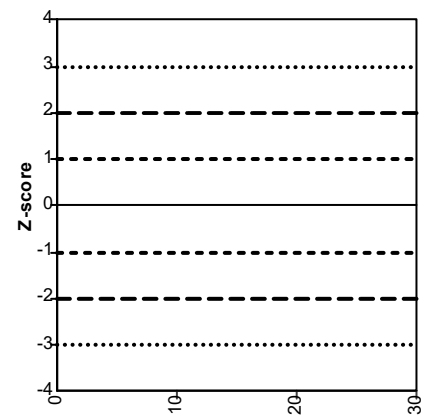
Bivariate Z-score plots (by survey)



Z-score history (by survey)

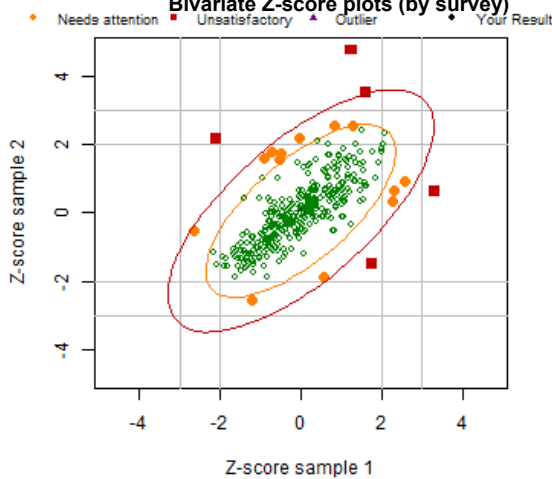


Z-score history (by consensus value)

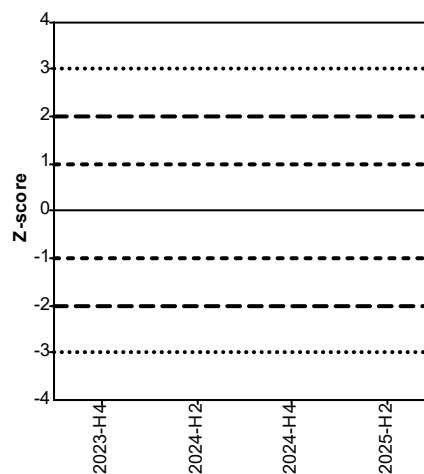


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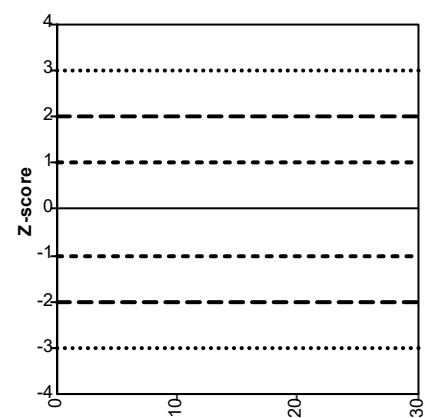
Bivariate Z-score plots (by survey)



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 25.115

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 25.0 BU/mL

Prior Use None

Unit BU/mL

Expiry Date 31-January-2028

Homogeneity 3.9 %

Homogeneity Parameter Factor VIII Inhibitor

For any method used for the measurement of this parameter with a $CV \leq 13.0\%$ 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 343

Number of Responders 320

Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis :

102: 1.2 BU/mL

3606: 0.4 BU/mL

6222: 160 BU/mL

3855: 89 BU/mL

Participants **610** and **1180** reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25.115 and 25.116.

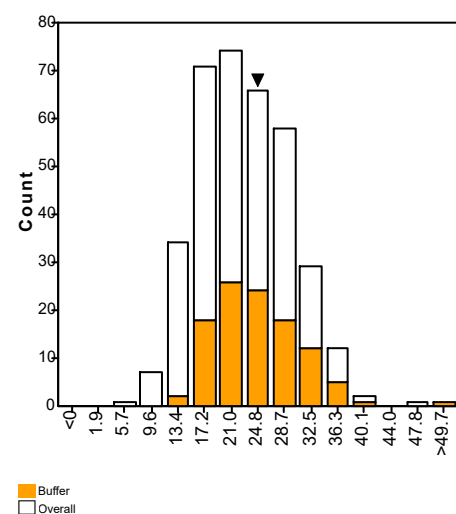
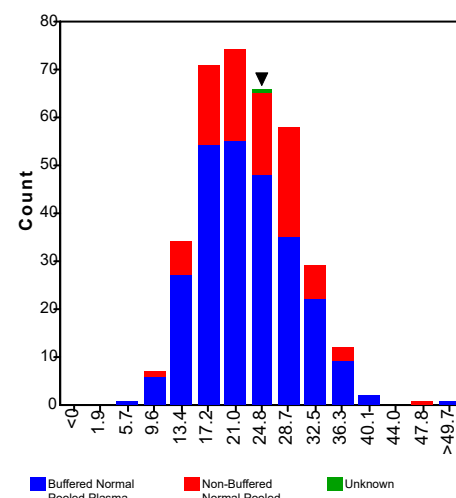
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	356	22.9	0.44	29.4	4.3 - 57.8	25.0	0.32				
Buffered Normal Pooled Plasma	260	22.5	0.53	30.1	4.3 - 57.8	25.0	0.36				
Buffer	107	24.7	0.74	24.8	15.0 - 57.8	25.0	0.06				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	356	22.9	0.44	29.4	4.3 - 57.8
Non-Buffered Normal Pooled Plasma	95	23.7	0.83	27.2	10.6 - 48.0
Buffer	55	23.4	0.99	25.2	12.0 - 35.3
Buffer + Albumin	2	26.3			22.5 - 30.1
Factor VIII Deficient Plasma	23	22.5	2.12	36.1	10.6 - 36.1
Heat-activated normal plasma	2	35.1			22.2 - 48.0
Other	12	25.7	1.99	21.5	16.6 - 35.2
Unknown	1	29.0			-
Buffered Normal Pooled Plasma	260	22.5	0.53	30.1	4.3 - 57.8
Buffer + Albumin	24	24.1	1.91	31.0	14.0 - 37.1
Factor VIII Deficient Plasma	96	19.6	0.84	33.5	4.3 - 35.6
Heat-inactivated normal plasma	17	21.7	2.36	35.9	9.0 - 38.3
Other	14	23.7	1.73	21.9	17.0 - 33.5
Unknown	2	22.9			18.9 - 26.8
Unknown	1	24.5			-
Buffer	1	24.5			-



Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)
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Sample No	25.116		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-January-2028		
Homogeneity	4.0 %	Homogeneity Parameter	Factor VIII Inhibitor
	For any method used for the measurement of this parameter with a $CV \leq 13.3\%$ 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	343		
Number of Responders	320	Response Rate	93 %
Comments	The following participants reported deviating results which were excluded from the statistical analysis :		
	126:	52.5	BU/mL
	1425:	38.40	BU/mL
	3855:	38	BU/mL
	3606:	0.0	BU/mL

Participants **610** and **1180** reported deviating results which were excluded from the statistical analysis. These results might be caused by an accidental mix-up of the sample 25. 115 and 25.116.

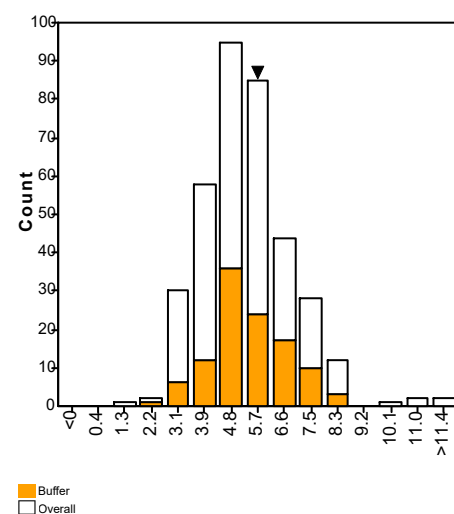
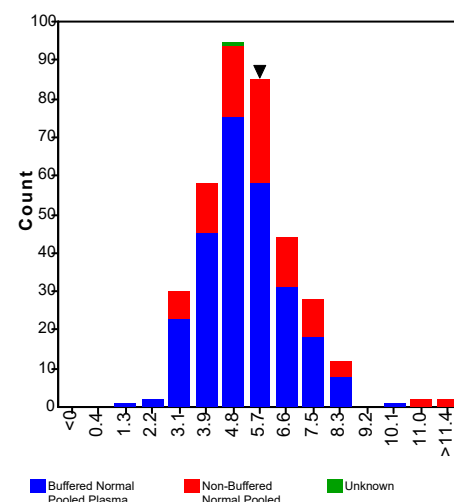
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	358	5.3	0.09	25.9	1.1 - 11.4	5.3	0.02				
Buffered Normal Pooled Plasma	262	5.2	0.10	25.3	1.1 - 9.8	5.3	0.11				
Buffer	109	5.4	0.15	23.1	2.5 - 8.4	5.3	-0.09				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	358	5.3	0.09	25.9	1.1 - 11.4
Non-Buffered Normal Pooled Plasma	95	5.6	0.19	26.0	2.7 - 11.4
Buffer	55	5.5	0.23	25.1	2.7 - 8.5
Buffer + Albumin	2	5.8			4.8 - 6.9
Factor VIII Deficient Plasma	24	5.4	0.41	30.0	3.1 - 8.5
Heat-activated normal plasma	2	5.9			5.4 - 6.4
Other	11	6.5	0.94	38.1	3.8 - 11.4
Unknown	1	6.0			-
Buffered Normal Pooled Plasma	262	5.2	0.10	25.3	1.1 - 9.8
Buffer + Albumin	25	5.4	0.32	23.6	3.4 - 9.8
Factor VIII Deficient Plasma	96	4.7	0.16	26.8	1.1 - 8.0
Heat-inactivated normal plasma	17	5.6	0.49	28.8	3.4 - 8.2
Other	13	5.4	0.25	13.2	4.6 - 8.0
Unknown	2	6.7			6.5 - 6.9
Unknown	1	5.0			-
Buffer	1	5.0			-

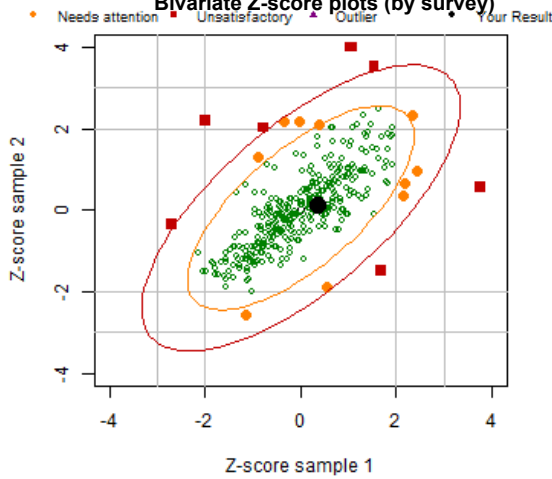


Factor VIII inhibitor

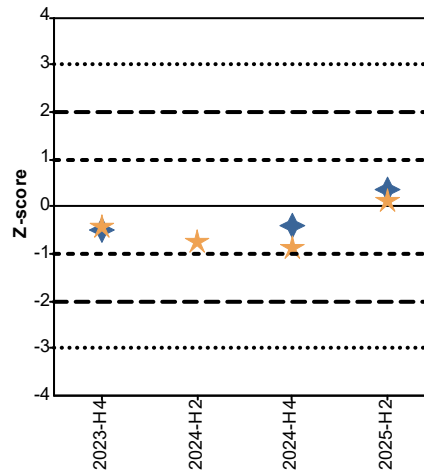
Factor VIII Inhibitor (by assay concept)

Instrument ID

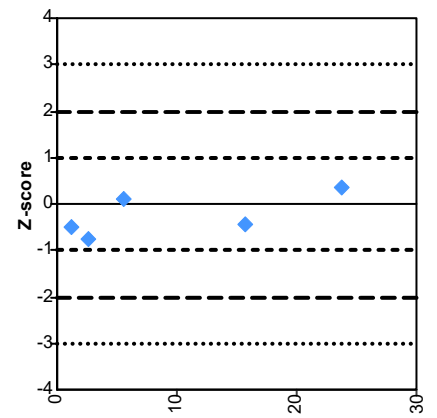
Bivariate Z-score plots (by survey)



Z-score history (by survey)

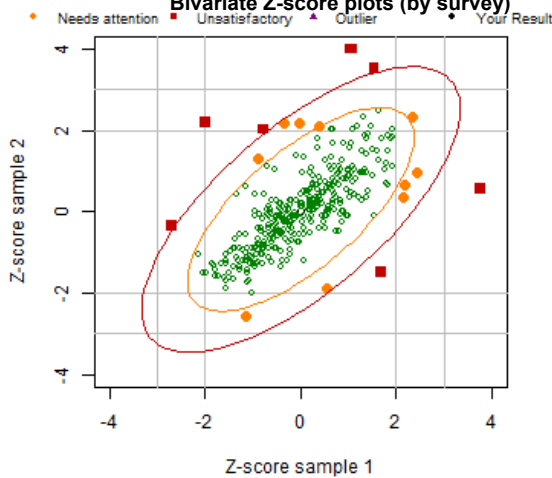


Z-score history (by consensus value)

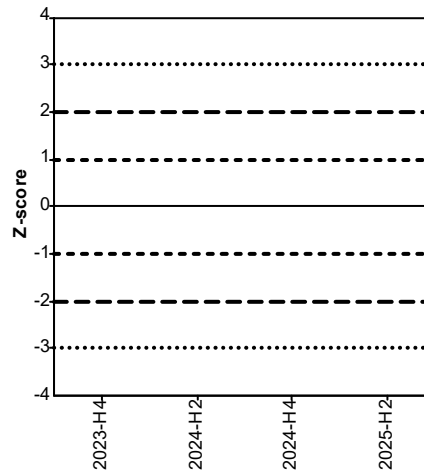


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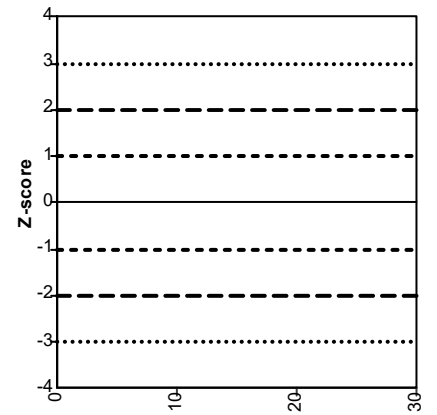
Bivariate Z-score plots (by survey)



Z-score history (by survey)

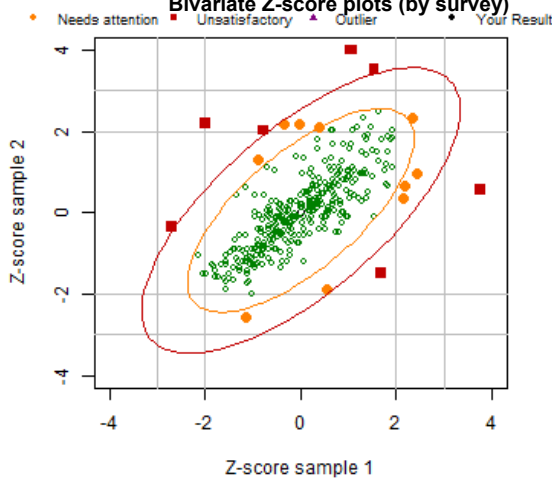


Z-score history (by consensus value)

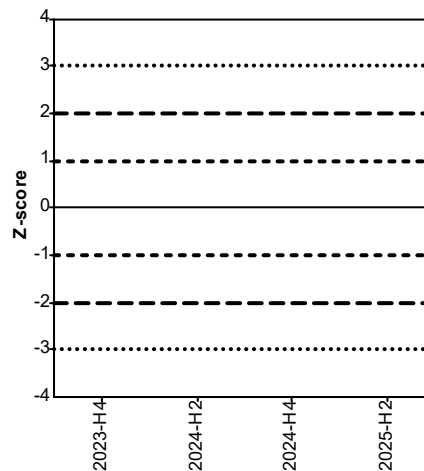


Instrument ID

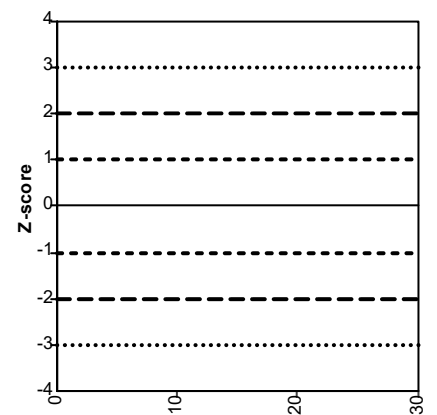
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



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

Sample No 25.115

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 25.0 BU/mL

Prior Use None

Unit BU/mL

Expiry Date 31-January-2028

Homogeneity 3.9 %

Homogeneity Parameter Factor VIII Inhibitor

For any method used for the measurement of this parameter with a $CV \leq 13.0\%$ 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 343

Number of Responders 320

Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis :

102: 1.2 BU/mL

3606: 0.4 BU/mL

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3855: 89 BU/mL

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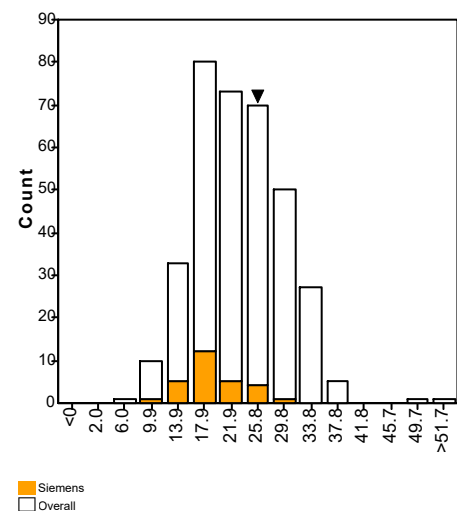
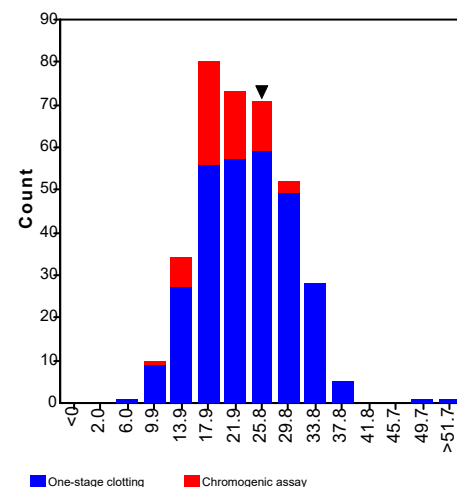
Participant **3828** has submitted three times the same result, suggesting that these are separate results. This is not the case and may affect the statistical analysis and therefore the second and third result were excluded.

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	356	22.9	0.44	29.4	4.3 - 57.8	25.0	0.32				
Chromogenic assay	63	20.2	0.70	22.1	11.9 - 29.3	25.0	1.08				
Siemens Factor VIII	28	18.8	1.09	24.6	11.9 - 29.3	25.0	1.35				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	356	22.9	0.44	29.4	4.3 - 57.8
One-stage clotting assay	293	23.5	0.51	29.9	4.3 - 57.8
Hemoliance Synthasil APTT	1	18.2			-
Hyphen Biomed Cephen	1	20.4			-
Roche APTT	1	31.2			-
Siemens Actin FS	48	20.4	1.14	31.0	10.9 - 35.2
Siemens Actin FSL	11	25.3	3.21	33.7	9.0 - 35.6
Siemens Pathromtin SL	32	23.3	1.40	27.3	11.9 - 38.3
Stago Cephalin/Kaolin/CK Prest	56	23.6	1.13	28.6	8.0 - 36.1
Stago PTT (automate)	9	22.0			16.0 - 57.8
Tcoag TriniClot APTT S	1	18.6			-
Tcoag TriniClot APTT-HS	2	23.6			21.1 - 26.0
Technoclone Dapttin	1	22.1			-
Werfen HemosIL APTT-SP liquid silica	2	17.5			16.5 - 18.4
Werfen HemosIL Synthasil	123	24.7	0.80	28.7	4.3 - 48.0
Chromogenic assay	63	20.2	0.70	22.1	11.9 - 29.3
Chromogenix Coamatic Factor VIII	14	21.5	1.10	15.3	16.8 - 27.0
Chromogenix Coatest SP Factor VIII	1	18.0			-
Hyphen Biomed Biophen Factor VIII	1	16.0			-
Other	3	15.6			13.1 - 22.3
Precision Biologic Cryocheck Chromog	7	19.5			16.4 - 24.5
TCoag Trinichrom FVIII	1	16.5			-
Technoclone Factor VIII	2	23.7			20.9 - 26.4
Werfen Electrachrome FVIII	6	24.6			22.6 - 28.3



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No 25.116

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 6.0 BU/mL

Prior Use None

Unit BU/mL

Expiry Date 31-January-2028

Homogeneity 4.0 %

Homogeneity Parameter Factor VIII Inhibitor

For any method used for the measurement of this parameter with a $CV \leq 13.3\%$ 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 343

Number of Responders 320

Response Rate 93 %

Comments The following participants reported deviating results which were excluded from the statistical analysis :

126: 52.5 BU/mL

1425: 38.40 BU/mL

3855: 38 BU/mL

3606: 0.0 BU/mL

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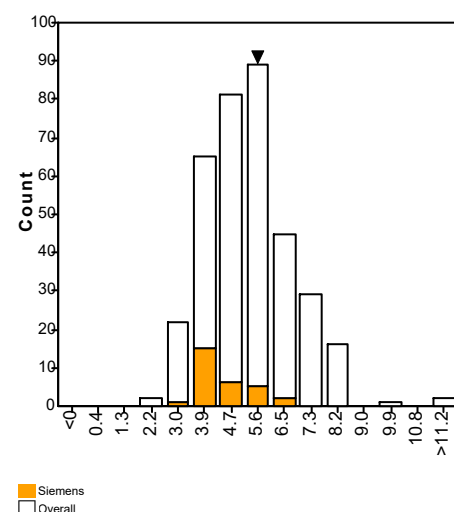
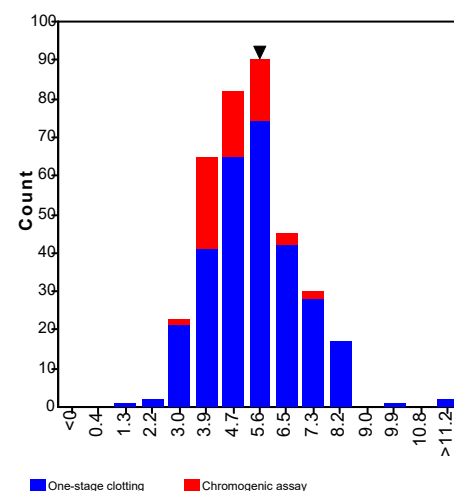
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Total Group	358	5.3	0.09	25.9	1.1 - 11.4	5.3	0.02				
Chromogenic assay	64	4.7	0.13	17.8	3.4 - 7.4	5.3	0.75				
Siemens Factor VIII	29	4.5	0.21	20.0	3.4 - 6.5	5.3	0.86				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	358	5.3	0.09	25.9	1.1 - 11.4
One-stage clotting assay	294	5.4	0.10	26.6	1.1 - 11.4
Hemoliance Synthasil APTT	1	5.1			-
Hyphen Biomed Cephen	1	5.2			-
Roche APTT	1	6.4			-
Siemens Actin FS	49	4.9	0.22	24.8	3.1 - 8.0
Siemens Actin FSL	11	6.2	0.55	23.5	4.4 - 8.0
Siemens Pathromtin SL	32	5.4	0.36	30.0	2.7 - 8.2
Stago Cephalin/Kaolin/CK Prest	56	5.4	0.23	25.7	2.7 - 11.4
Stago PTT (automate)	10	5.2	0.25	12.1	4.2 - 6.1
Tcoag TriniClot APTT S	1	4.3			-
Tcoag TriniClot APTT-HS	2	4.9			4.7 - 5.0
Technoclone Dapttin	1	5.0			-
Werfen HemosIL APTT-SP liquid silica	2	4.8			4.1 - 5.5
Werfen HemosIL SynthASil	121	5.6	0.17	27.1	1.8 - 9.8
Chromogenic assay	64	4.7	0.13	17.8	3.4 - 7.4
Chromogenix Coamatic Factor VIII	13	4.8	0.25	14.9	4.0 - 7.4
Chromogenix Coatest SP Factor VIII	1	4.0			-
Hyphen Biomed Biophen Factor VIII	1	4.2			-
Other	3	4.0			3.4 - 4.4
Precision Biologic Cryocheck Chromog	8	4.7			4.0 - 5.4
TCoag Trinichrom FVIII	1	4.6			-
Technoclone Factor VIII	2	5.1			4.8 - 5.3
Werfen Electrachrome FVIII	6	5.4			5.3 - 7.2



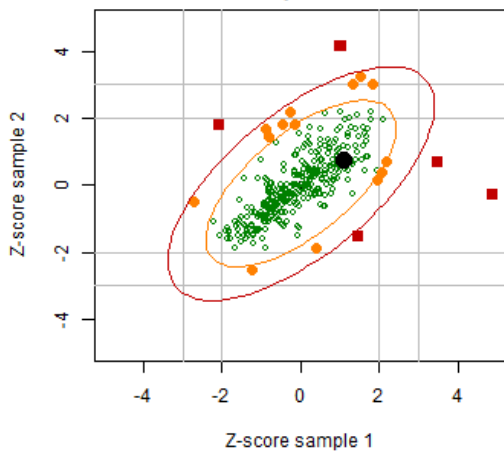
Factor VIII inhibitor

Factor VIII Inhibitor (by FVIII assay)

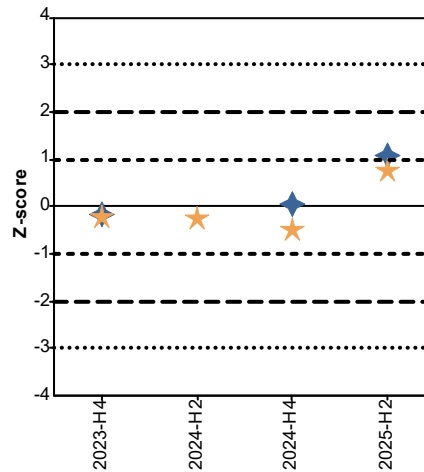
Instrument ID

Bivariate Z-score plots (by survey)

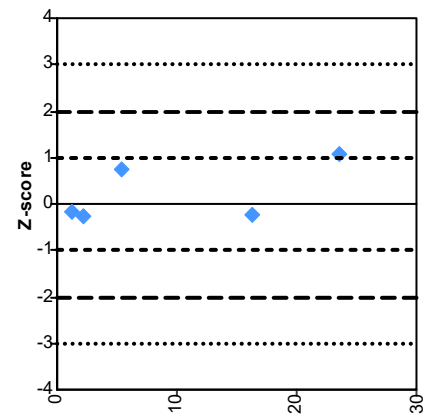
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



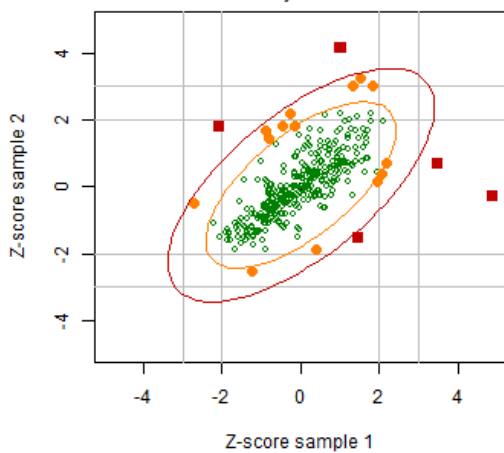
Z-score history (by consensus value)



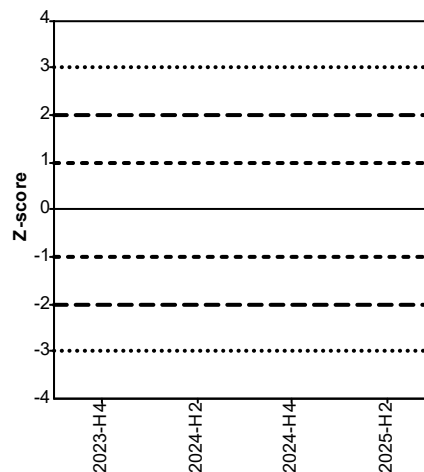
Instrument ID

Bivariate Z-score plots (by survey)

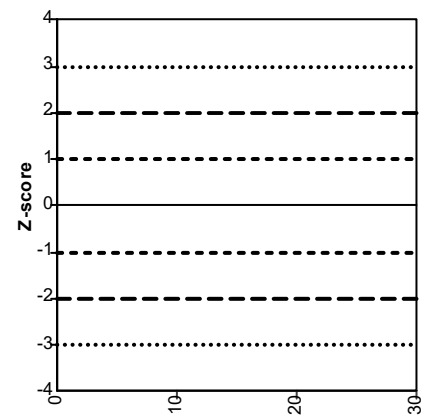
Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



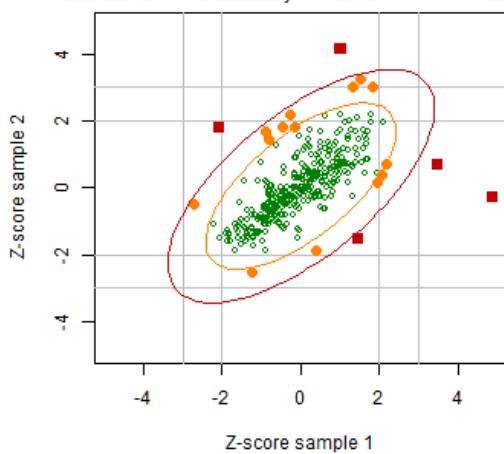
Z-score history (by consensus value)



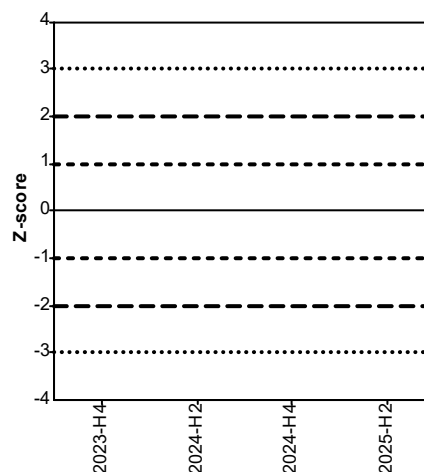
Instrument ID

Bivariate Z-score plots (by survey)

Needs attention Unsatisfactory Outlier Your Result



Z-score history (by survey)



Z-score history (by consensus value)

