

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-H4

Haemophilia

Labcode 1492

Date of Issue : 23-januari-2024

Survey : 2023-H4

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 **March 5th, 2024**.

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

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.

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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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 inhibitor assay conc	23.209	1	-0.55	-0.49	-0.43		
		23.210	1	-0.50	-0.43	-0.85		
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	23.209	1	-0.55	-0.16	-0.52		
		23.210	1	-0.50	-0.23	-0.54		
Factor VIII inhibitor	Factor VIII Inhibitor (Manufacturer)	23.209	1	-0.55	-0.47			
		23.210	1	-0.50	-0.44			

Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 23.209
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 1.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 2.0 %

Homogeneity Parameter Factor VIII 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 359
Number of Responders 331 **Response Rate** 92 %

Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participants reported deviating results which were excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:

- 9907122 (instr.1)** : 10.8 BU/mL
- 9907122 (instr.2)** : 9.1 BU/mL
- 9907288** : 25.5 BU/mL

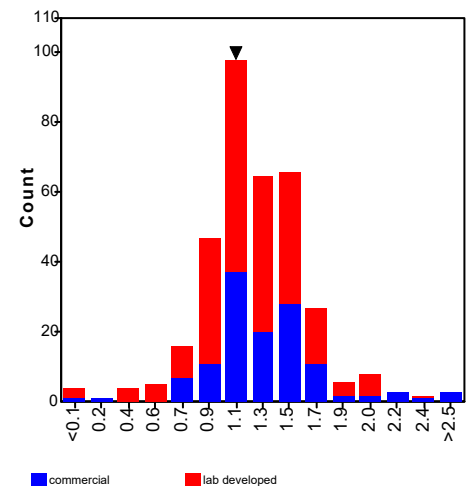
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your	z-score	your	z-score	your	z-score
						result		result		result	
Lab-developed test	228	1.2	0.02	22.1	0.0 - 2.4	1.1	-0.47				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Commercial Test	127	1.3	0.03	22.2	0.0 - 2.8
Other	71	1.3	0.05	24.0	0.0 - 2.8
Precision Biologics	20	1.2	0.07	21.5	0.8 - 1.7
Technoclone	36	1.4	0.05	19.3	0.1 - 2.6
Lab-developed test	228	1.2	0.02	22.1	0.0 - 2.4



Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)
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Sample No 23.210
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 14.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 0.0 % **Homogeneity Parameter** Factor VIII Inhibitor
Number of Participants 359 **Response Rate** 92 %
Number of Responders 331
Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participant reported a deviating result which was excluded in the statistical evaluation:
137 : 1.45 BU/mL

The following participants reported deviating results which were excluded in the statistical evaluation.
This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:

9907122 (instr.1) : 0.66 BU/mL
9907122 (instr.2) : 0.79 BU/mL
9907288 : 1.6 BU/mL

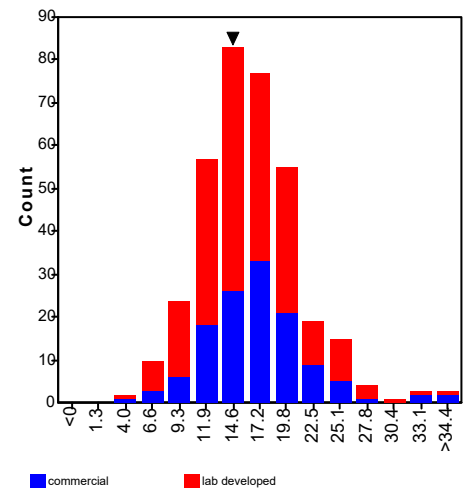
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result		your result		your result	
						z-score	z-score	z-score	z-score		
Lab-developed test	226	15.7	0.37	28.1	5.1 - 52.8	13.8	-0.44				

Other Reagents

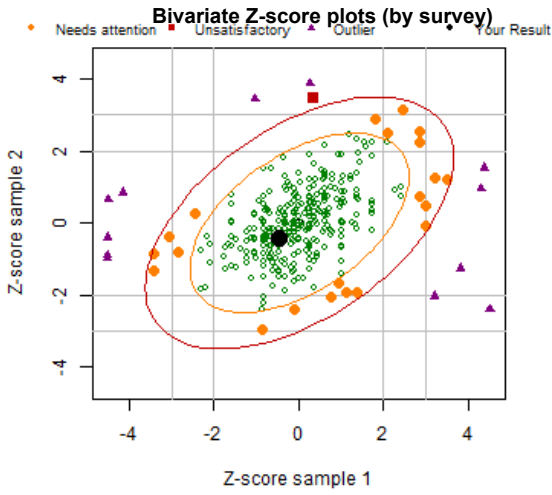
	n	assigned value	Uncert.	CV (%)	Range
Commercial Test	127	16.6	0.49	26.8	3.5 - 58.0
Other	72	15.6	0.62	27.1	3.5 - 32.0
Precision Biologics	20	17.6	1.38	28.0	11.8 - 58.0
Technoclone	35	18.2	0.86	22.5	8.2 - 27.5
Lab-developed test	226	15.7	0.37	28.1	5.1 - 52.8



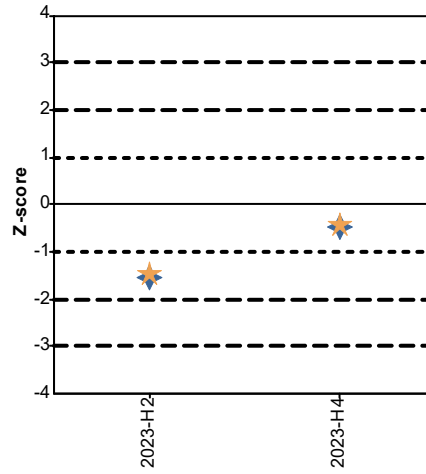
Factor VIII inhibitor

Factor VIII Inhibitor (by type of test)

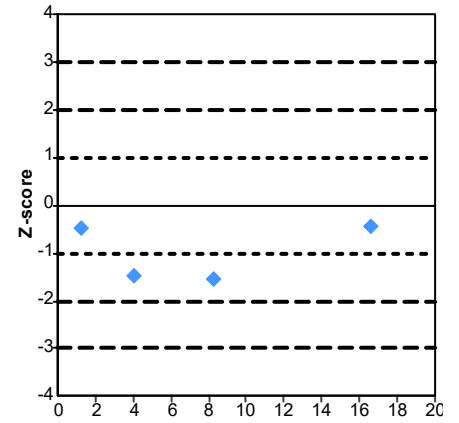
Instrument ID



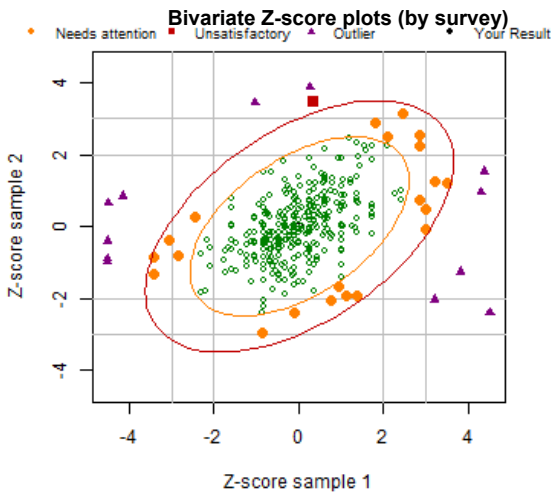
Z-score history (by survey)



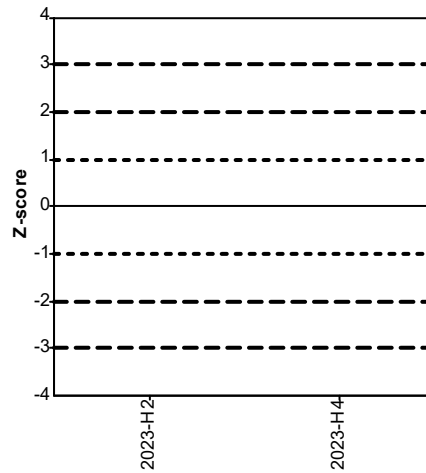
Z-score history (by consensus value)



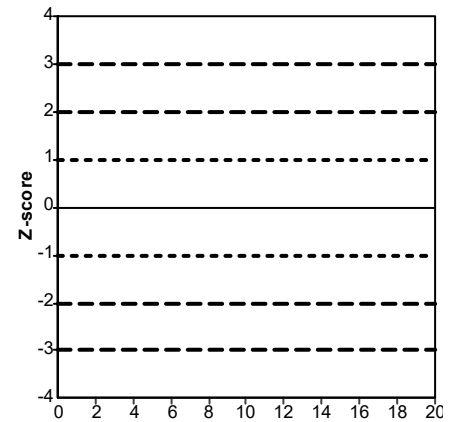
Instrument ID



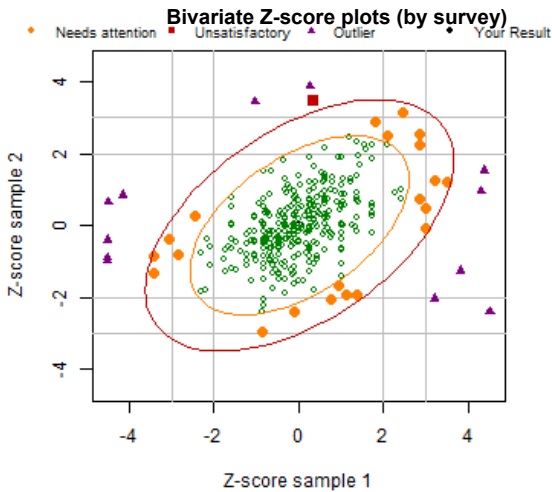
Z-score history (by survey)



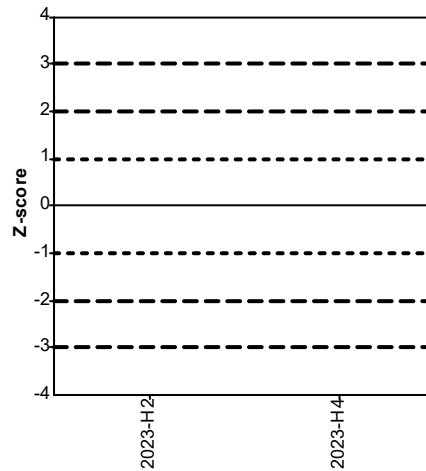
Z-score history (by consensus value)



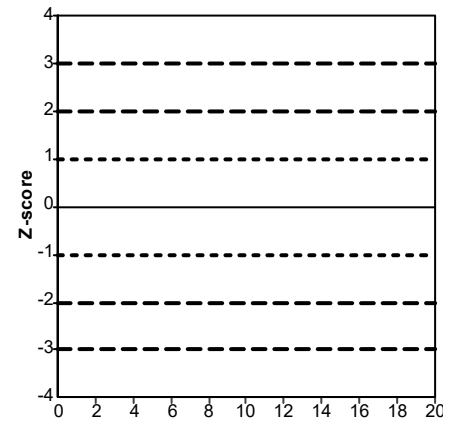
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor	Factor VIII Inhibitor (by inhibitor assay concept)
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Sample No 23.209
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 1.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 2.0 % **Homogeneity Parameter** Factor VIII Inhibitor
 For any method used for the measurement of this parameter with a $CV \leq 6.7\%$ 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 359
Number of Responders 331 **Response Rate** 92 %

Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participants reported deviating results which were excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:
9907122 (instr.1) : 10.8 BU/mL
9907122 (instr.2) : 9.1 BU/mL
9907288 : 25.5 BU/mL

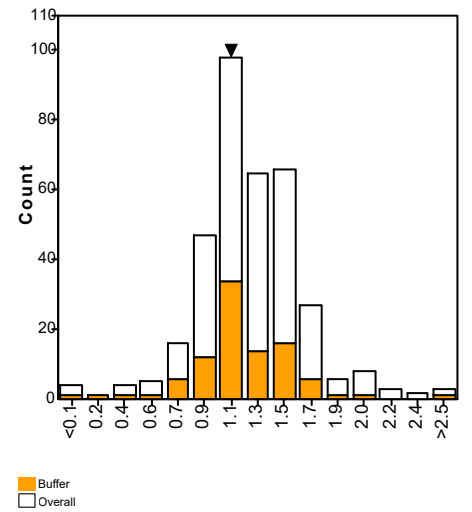
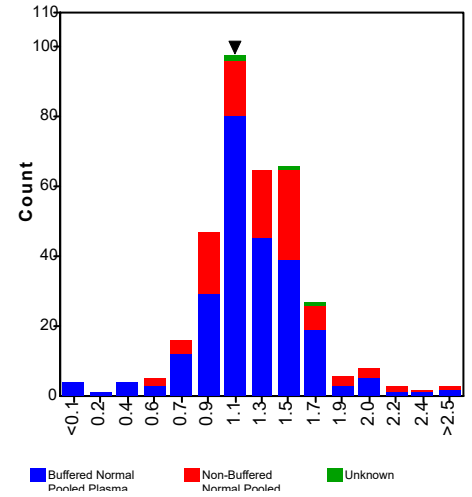
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Buffered Normal Pooled Plasma	248	1.2	0.02	21.9	0.0 - 2.6	1.1	-0.49				
Buffer	95	1.2	0.03	21.2	0.0 - 2.6	1.1	-0.43				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Non-Buffered Normal Pooled Plasma	103	1.3	0.04	23.1	0.6 - 2.8
Buffer	59	1.3	0.05	24.1	0.8 - 2.4
Buffer + Albumin	1	1.5			-
Factor VIII Deficient Plasma	22	1.3	0.08	21.8	1.0 - 2.8
Heat-activated normal plasma	3	1.3			1.2 - 1.5
Other	14	1.3	0.16	36.6	0.6 - 2.0
Unknown	4	1.3			1.0 - 1.5
Buffered Normal Pooled Plasma	248	1.2	0.02	21.9	0.0 - 2.6
Buffer + Albumin	27	1.4	0.09	28.3	0.8 - 2.2
Factor VIII Deficient Plasma	98	1.2	0.03	20.3	0.0 - 2.6
Heat-inactivated normal plasma	17	1.3	0.12	30.8	0.6 - 1.8
Other	11	1.3	0.10	21.1	0.8 - 1.7
Unknown	4	1.3			1.2 - 1.6
Buffer	2	1.2			1.2 - 1.2
Factor VIII Deficient Plasma	2	1.5			1.4 - 1.6



Factor VIII inhibitor	Factor VIII Inhibitor (by inhibitor assay concept)
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Sample No 23.210
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 14.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 0.0 % **Homogeneity Parameter** Factor VIII Inhibitor
Number of Participants 359 **Response Rate** 92 %
Number of Responders 331
Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participant reported a deviating result which was excluded in the statistical evaluation:
137 : 1.45 BU/mL

The following participants reported deviating results which were excluded in the statistical evaluation.
 This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:

9907122 (instr.1) : 0.66 BU/mL
9907122 (instr.2) : 0.79 BU/mL
9907288 : 1.6 BU/mL

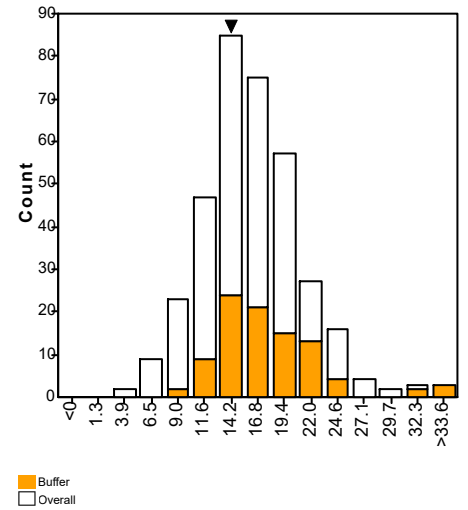
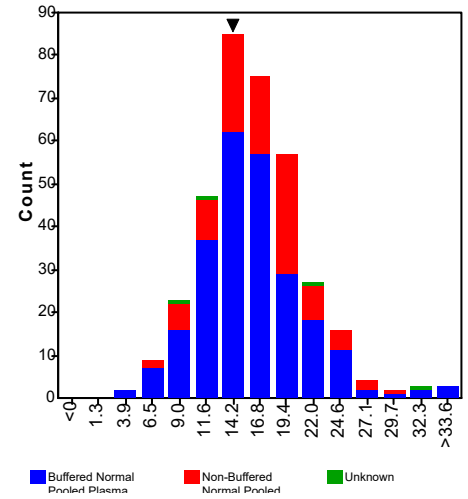
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Buffered Normal Pooled Plasma	247	15.7	0.35	27.9	3.5 - 58.0	13.8	-0.43				
Buffer	93	17.3	0.54	23.9	9.9 - 58.0	13.8	-0.85				

Other Reagents

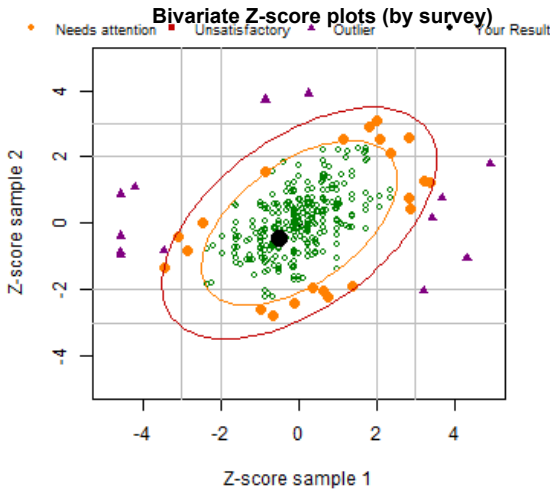
	n	assigned value	Uncert.	CV (%)	Range
Non-Buffered Normal Pooled Plasma	102	16.8	0.52	24.9	6.0 - 29.7
Buffer	60	16.9	0.59	21.5	6.0 - 29.7
Buffer + Albumin	1	19.5			-
Factor VIII Deficient Plasma	20	15.2	1.58	37.1	8.0 - 25.0
Heat-activated normal plasma	3	18.4			16.5 - 19.6
Other	14	19.1	1.61	25.2	13.0 - 25.6
Unknown	4	12.4			7.5 - 19.0
Buffered Normal Pooled Plasma	247	15.7	0.35	27.9	3.5 - 58.0
Buffer + Albumin	27	19.0	1.15	25.2	12.5 - 28.5
Factor VIII Deficient Plasma	99	13.5	0.48	28.2	3.5 - 25.6
Heat-inactivated normal plasma	17	14.8	1.60	35.5	7.6 - 26.7
Other	11	15.7	1.19	20.1	11.0 - 19.6
Unknown	4	17.2			8.0 - 32.0
Buffer	2	17.2			11.9 - 22.4
Factor VIII Deficient Plasma	2	20.0			8.0 - 32.0



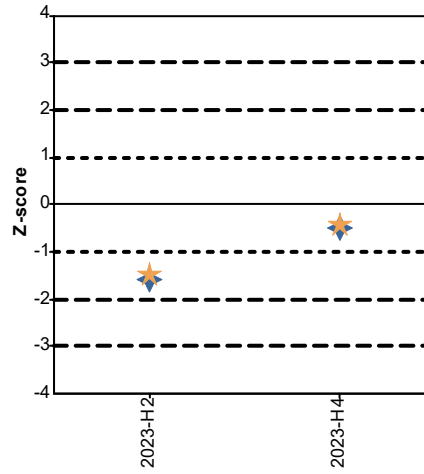
Factor VIII inhibitor

Factor VIII Inhibitor (by inhibitor assay concept)

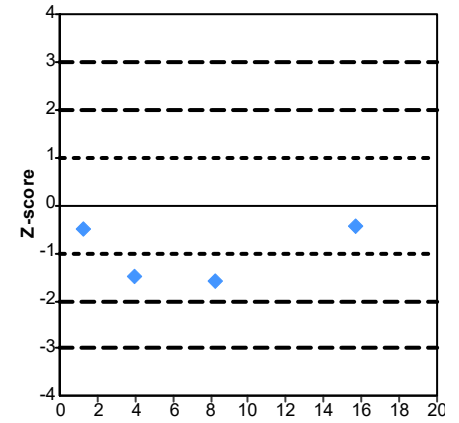
Instrument ID



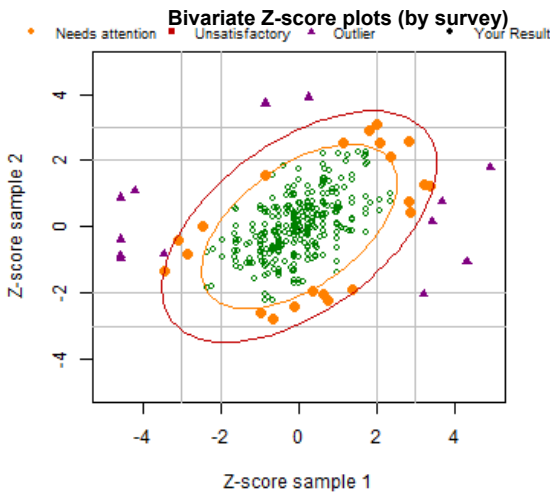
Z-score history (by survey)



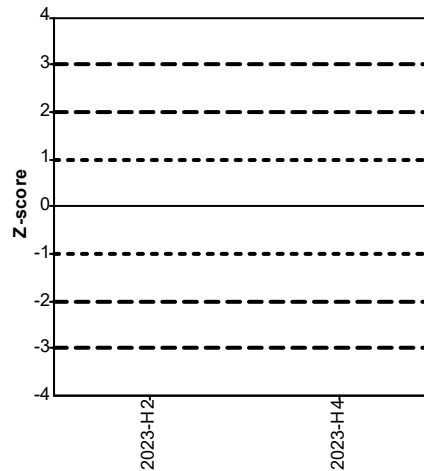
Z-score history (by consensus value)



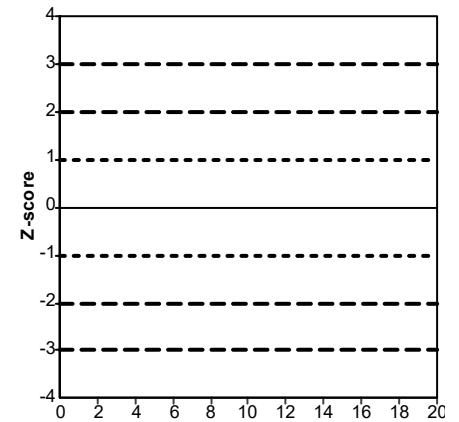
Instrument ID



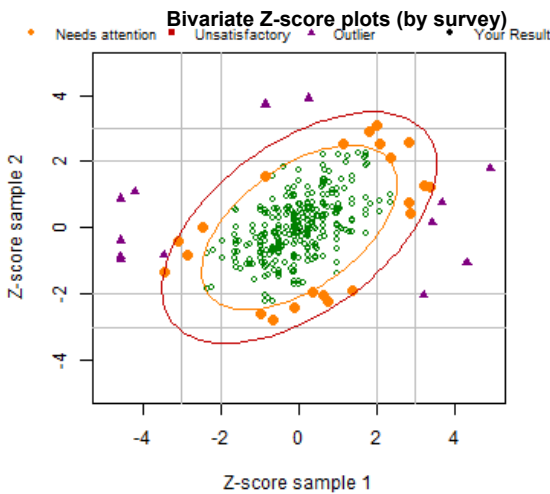
Z-score history (by survey)



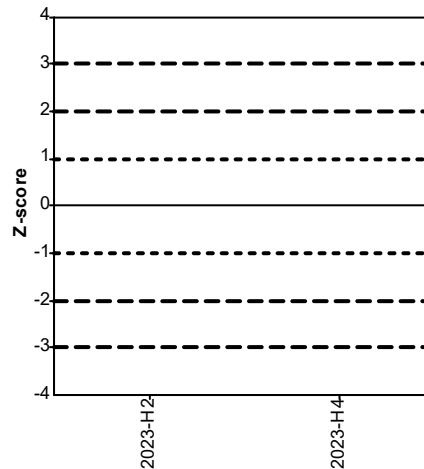
Z-score history (by consensus value)



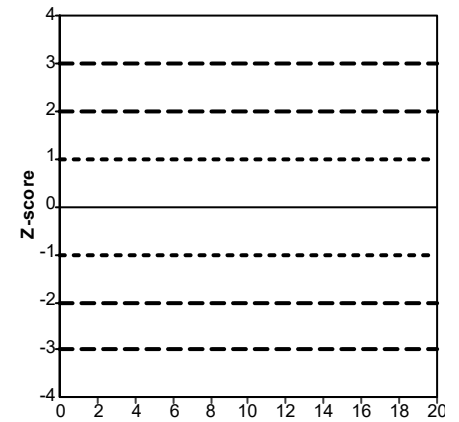
Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor

Factor VIII Inhibitor (by FVIII assay)

Sample No 23.209
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 1.0 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 2.0 % **Homogeneity Parameter** Factor VIII Inhibitor
 For any method used for the measurement of this parameter with a $CV \leq 6.7\%$ 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 359
Number of Responders 331 **Response Rate** 92 %

Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participants reported deviating results which were excluded in the statistical evaluation. This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:
9907122 (instr.1) : 10.8 BU/mL
9907122 (instr.2) : 9.1 BU/mL
9907288 : 25.5 BU/mL

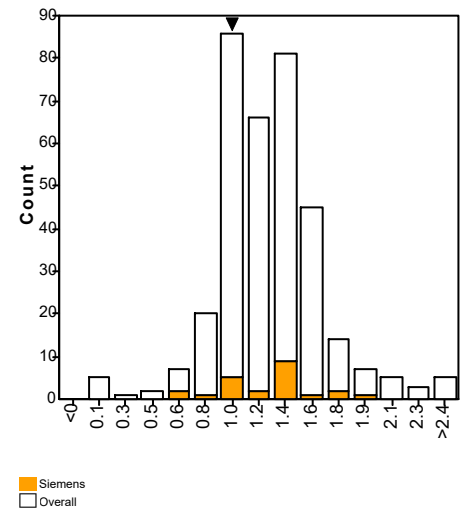
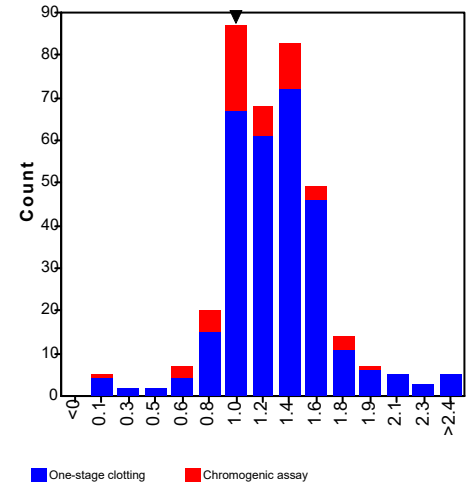
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Chromogenic assay	54	1.1	0.05	24.2	0.1 - 2.0	1.1	-0.16				
Siemens Factor VIII	23	1.3	0.08	24.6	0.6 - 2.0	1.1	-0.52				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
One-stage clotting assay	301	1.3	0.02	21.5	0.0 - 2.8
Hemoliance Synthasil APTT	2	1.9			1.6 - 2.2
Hyphen Biomed Cephen	2	1.4			1.4 - 1.4
IL HemosIL APTT lyophilised silica	3	1.3			1.2 - 1.6
IL HemosIL APTT-SP liquid silica	4	1.1			0.8 - 1.8
IL HemosIL SynthASil	107	1.3	0.04	25.5	0.0 - 2.4
Other	1	1.2			-
Roche APTT	2	1.0			1.0 - 1.0
Siemens Actin FS	49	1.2	0.03	13.2	0.3 - 2.6
Siemens Actin FSL	9	1.4			1.0 - 1.7
Siemens Pathromtin SL	42	1.3	0.06	25.9	0.0 - 2.6
Stago Cephalin/Kaolin/CK Prest	50	1.3	0.04	17.1	0.9 - 2.0
Stago PTT (automate)	14	1.3	0.07	15.0	0.4 - 2.8
Tcoag Automated APTT	1	1.0			-
Tcoag TriniClot APTT S	2	1.0			1.0 - 1.1
Tcoag TriniClot APTT-HS	2	1.1			0.9 - 1.2
Technoclone Dapttin	1	1.5			-
Technoclone Siron LS	1	0.7			-
Chromogenic assay	54	1.1	0.05	24.2	0.1 - 2.0
Chromogenix Coamatic Factor VIII	9	1.0			1.0 - 1.5
Chromogenix Coatest SP Factor VIII	3	1.0			0.8 - 1.1
Hyphen Biomed Biophen Factor VIII	3	1.0			0.1 - 1.2
IL Electrachrome FVIII	3	1.1			1.0 - 1.2
Other	2	0.8			0.6 - 1.1
Precision Biologic Cryocheck Chromog	5	1.0			0.8 - 1.4
TCoag Trinichrom FVIII	1	1.3			-
Technoclone Factor VIII	4	1.1			0.8 - 1.8



Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)
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Sample No 23.210
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 14.5 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 30-april-2026
Homogeneity 0.0 % **Homogeneity Parameter** Factor VIII Inhibitor
Number of Participants 359 **Response Rate** 92 %
Number of Responders 331
Comments The following participants **1350, 1425, 3816, 3828** and **3850** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participant reported a deviating result which was excluded in the statistical evaluation:
137 : 1.45 BU/mL

The following participants reported deviating results which were excluded in the statistical evaluation.
 This result might be caused by an accidental mix-up of the sample 23.209 and 23.210:

9907122 (instr.1) : 0.66 BU/mL
9907122 (instr.2) : 0.79 BU/mL
9907288 : 1.6 BU/mL

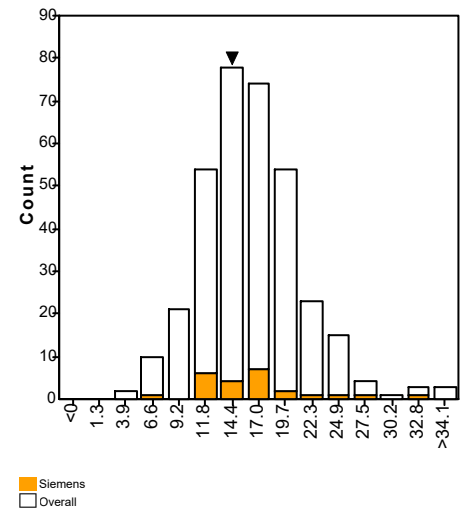
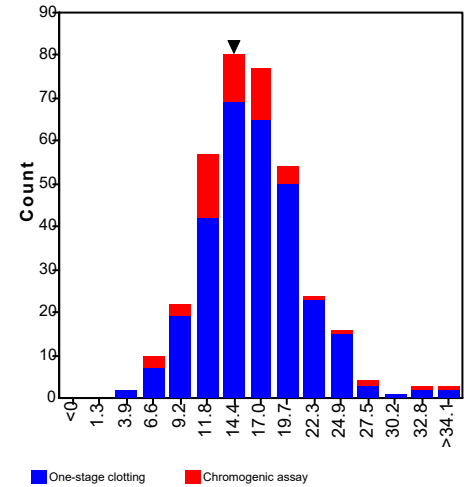
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Chromogenic assay	53	14.7	0.66	26.2	5.9 - 55.0	13.8	-0.23				
Siemens Factor VIII	24	16.2	1.15	27.7	7.8 - 32.0	13.8	-0.54				

Other Reagents

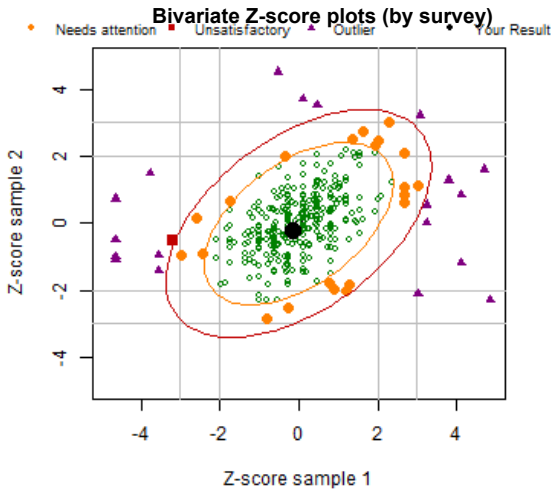
	n	assigned value	Uncert.	CV (%)	Range
One-stage clotting assay	300	16.3	0.32	27.5	3.5 - 58.0
Hemoliance Synthasil APTT	2	20.7			16.3 - 25.2
Hyphen Biomed Cephen	2	19.6			19.2 - 20.0
IL HemosIL APTT lyophilised silica	3	15.0			13.6 - 18.8
IL HemosIL APTT-SP liquid silica	4	15.4			8.9 - 18.1
IL HemosIL Synthasil	105	17.1	0.61	29.0	3.5 - 52.8
Other	1	17.7			-
Roche APTT	2	15.9			13.7 - 18.0
Siemens Actin FS	49	14.7	0.69	26.1	6.0 - 24.1
Siemens Actin FSL	9	18.9			6.0 - 25.2
Siemens Pathromtin SL	42	16.2	0.93	29.9	6.0 - 32.0
Stago Cephalin/Kaolin/CK Prest	50	16.5	0.74	25.5	8.2 - 58.0
Stago PTT (automate)	14	15.8	1.20	22.8	7.5 - 19.9
Tcoag Automated APTT	1	15.0			-
Tcoag TriniClot APTT S	2	12.3			10.5 - 14.0
Tcoag TriniClot APTT-HS	2	15.3			14.6 - 16.0
Technoclone Dapttin	1	21.0			-
Technoclone Siron LS	1	11.7			-
Chromogenic assay	53	14.7	0.66	26.2	5.9 - 55.0
Chromogenix Coamatic Factor VIII	9	12.0			5.9 - 55.0
Chromogenix Coatest SP Factor VIII	3	10.2			10.0 - 12.0
Hyphen Biomed Biophen Factor VIII	3	14.0			12.3 - 20.4
IL Electrachrome FVIII	2	15.6			14.7 - 16.5
Other	2	10.3			7.6 - 13.0
Precision Biologic Cryocheck Chromog	5	13.9			11.8 - 17.6
TCoag Trinichrom FVIII	1	14.6			-
Technoclone Factor VIII	3	15.8			13.3 - 19.3



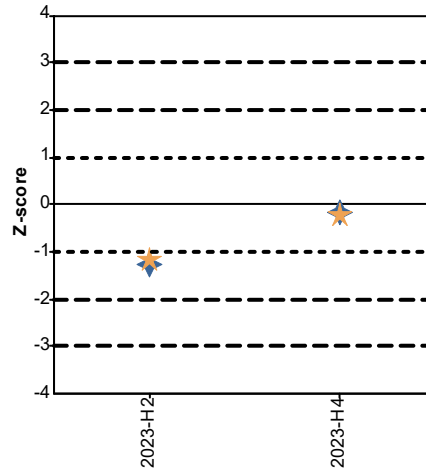
Factor VIII inhibitor

Factor VIII Inhibitor (by FVIII assay)

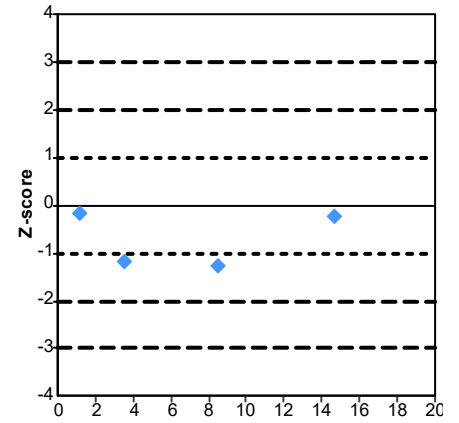
Instrument ID



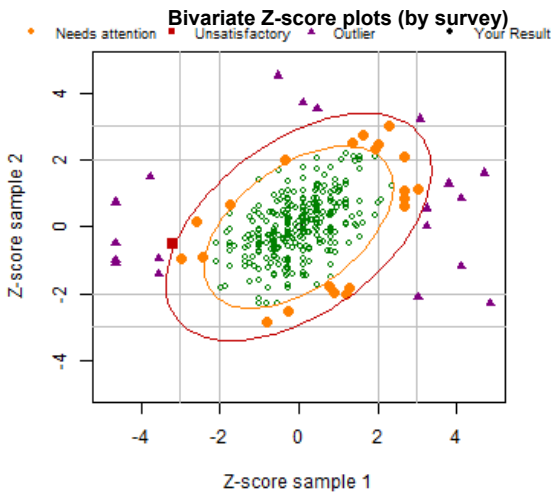
Z-score history (by survey)



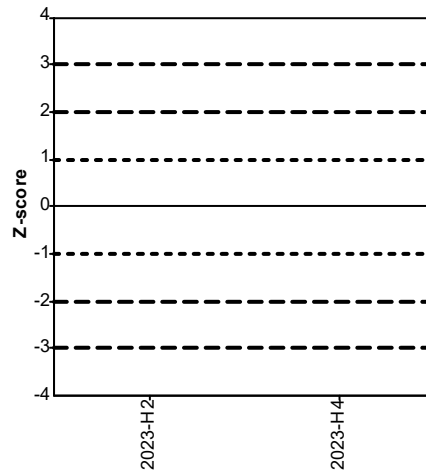
Z-score history (by consensus value)



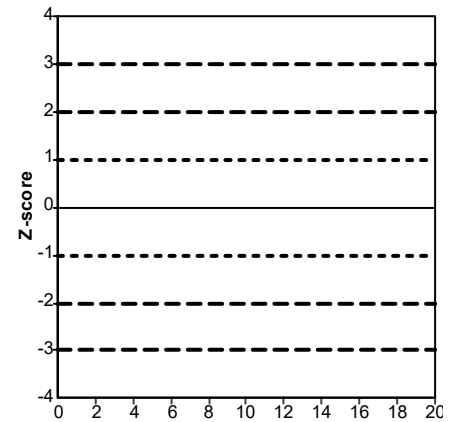
Instrument ID



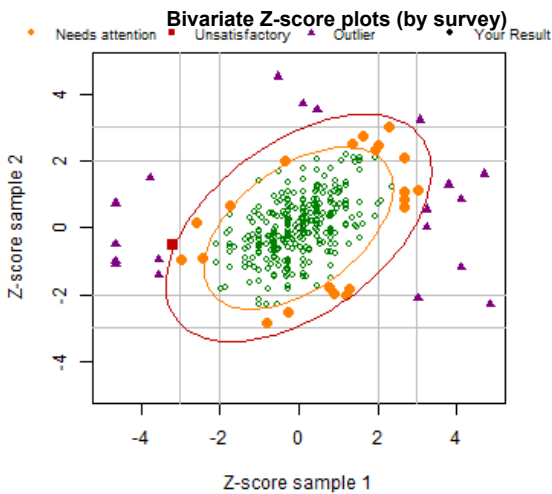
Z-score history (by survey)



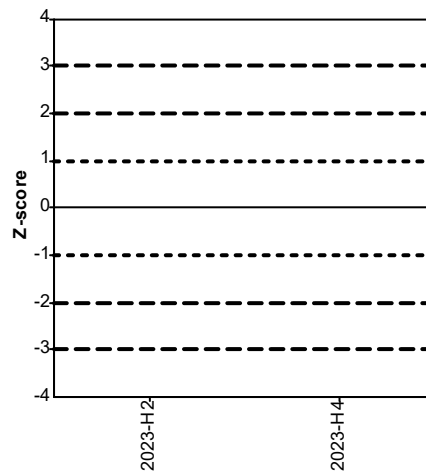
Z-score history (by consensus value)



Instrument ID



Z-score history (by survey)



Z-score history (by consensus value)

