ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2024-H2
Haemophilia
Labcode 1492

Date of Issue : 29-July-2024

Survey : 2024-H2

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

Complaints
Any complaints regarding this survey report should be reported to the ECAT before **September 19th, 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.

Emicizumab, Esperoct, NovoEight and Refixia
Because of the limited number of results for these parameters, the minimum number used for the calculation of the CV and Z-score is 5.

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

Director: Dr. P. Meijer
ECAT Office
P.O. Box 107
2250 AC Voorschoten, The Netherlands
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919
E-mail: info@ecat.nl
Website: www.ecat.nl
VAT number: NL802836872B01

Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
General terms of delivery are applicable to all our services.

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	Bivarate Analysis
Factor VIII inhibitor	Factor VIII Inhibitor (by type of test)	24.116	1	-0.82	-0.79		
Factor VIII inhibitor	Factor VIII Inhibitor (by assay concept)	24.116	1	-0.82	-0.75	-1.28	
Factor VIII inhibitor	Factor VIII Inhibitor (by FVIII assay)	24.116	1	-0.82	-0.26	0.08	

Factor VIII inhibitor

Factor VIII Inhibitor (by type of test)

Sample No	24.115
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 0.7 BU/mL
Prior Use	None
Unit	BU/mL
Expiry Date	31-January-2027
Homogeneity	0.0 %
Homogeneity Parameter	FVIII inhibitor
Number of Participants	342
Number of Responders	314
Response Rate	92 %
Comments	Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

Classification Overview	Negative	Equivocal	Positive
Total	74	66	207

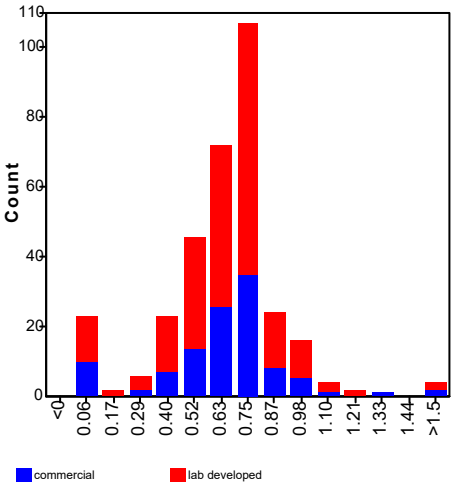
Your Classification Negative

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	330	0.7	0.01	30.4	0.0 - 2.2	<0.6					
Lab-developed test	219	0.7	0.02	30.4	0.0 - 2.2	<0.6					

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	330	0.7	0.01	30.4	0.0 - 2.2
Commercial Test	111	0.7	0.02	30.7	0.0 - 1.9
Other	62	0.6	0.04	35.3	0.0 - 1.7
Precision Biologics	20	0.6	0.05	29.2	0.0 - 1.9
Technoclone	29	0.7	0.03	20.7	0.0 - 1.1
Lab-developed test	219	0.7	0.02	30.4	0.0 - 2.2



Factor VIII inhibitor

Factor VIII Inhibitor (by type of test)

Sample No 24.116

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 2.6 BU/mL

Prior Use None

Unit BU/mL

Expiry Date 31-January-2027

Homogeneity 1.6 % **Homogeneity Parameter** FVIII inhibitor

For any method used for the measurement of this parameter with a **CV ≤ 5.3%** 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 342

Number of Responders 314 **Response Rate** 92 %

Comments Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

The following participant reported a deviating result which was excluded in the statistical evaluation:
3815 : 0 BU/mL

Classification Overview	Negative	Equivocal	Positive
Total	4	0	342

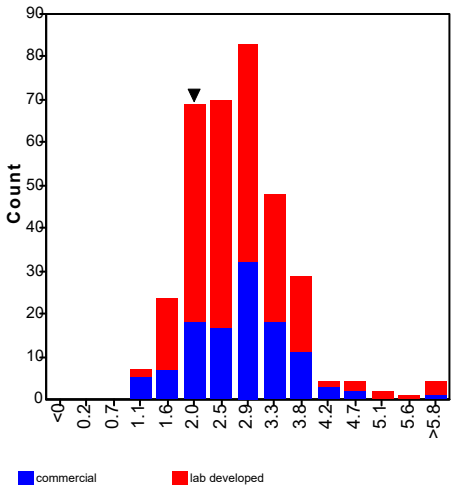
Your Classification Positive

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	345	2.7	0.05	27.0	1.2 - 8.0	2.1	-0.82				
Lab-developed test	231	2.7	0.06	26.5	1.3 - 8.0	2.1	-0.79				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	345	2.7	0.05	27.0	1.2 - 8.0
Commercial Test	114	2.8	0.09	27.6	1.2 - 7.6
Other	65	2.6	0.14	33.9	1.2 - 4.6
Precision Biologics	21	2.7	0.22	30.2	1.7 - 7.6
Technoclone	28	3.1	0.09	12.0	2.3 - 4.6
Lab-developed test	231	2.7	0.06	26.5	1.3 - 8.0

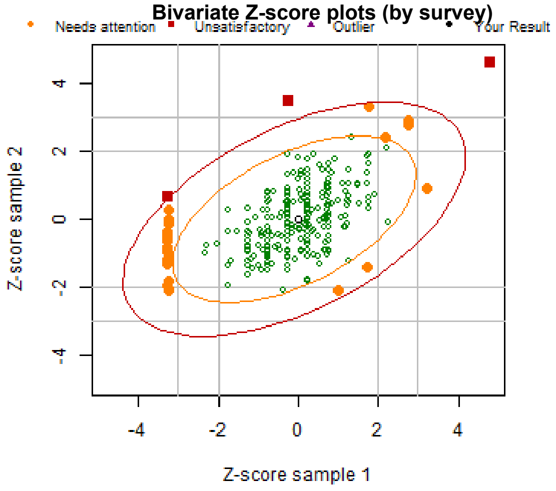


Factor VIII inhibitor

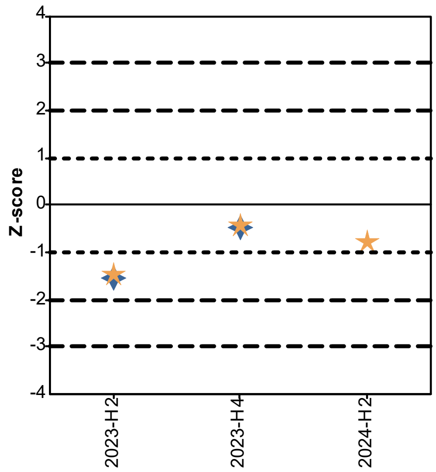
Factor VIII Inhibitor (by type of test)

Instrument ID	

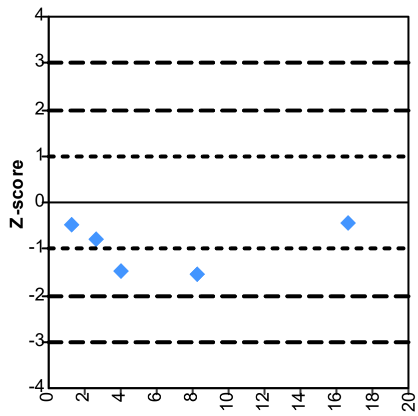
Bivariate Z-score plots (by survey)



Z-score history (by survey)

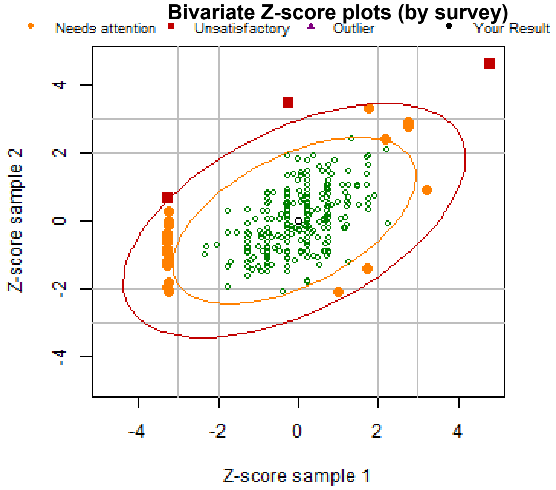


Z-score history (by consensus value)

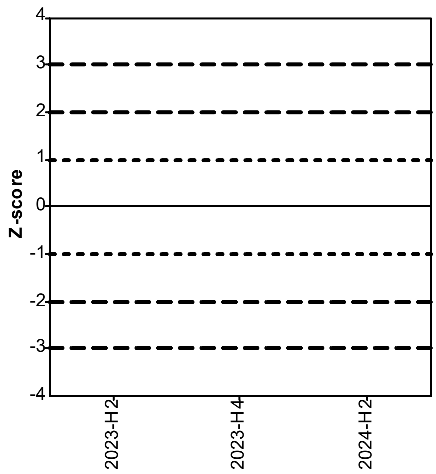


Instrument ID	

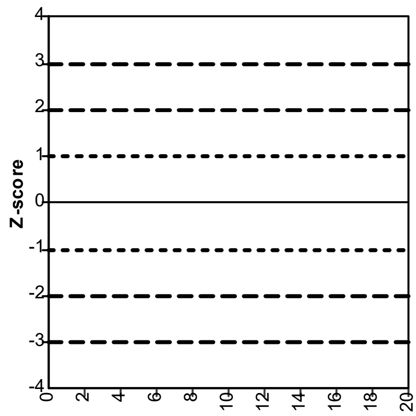
Bivariate Z-score plots (by survey)



Z-score history (by survey)

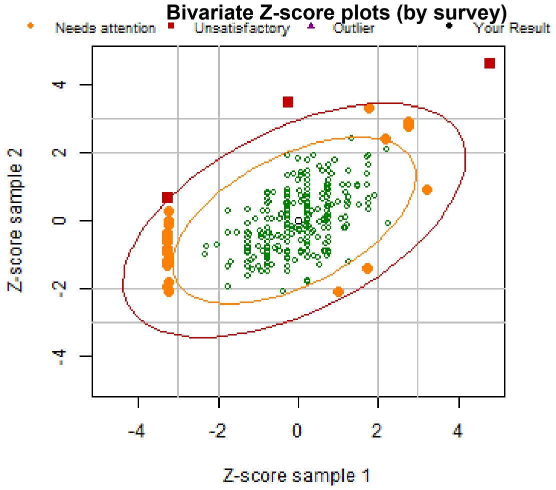


Z-score history (by consensus value)

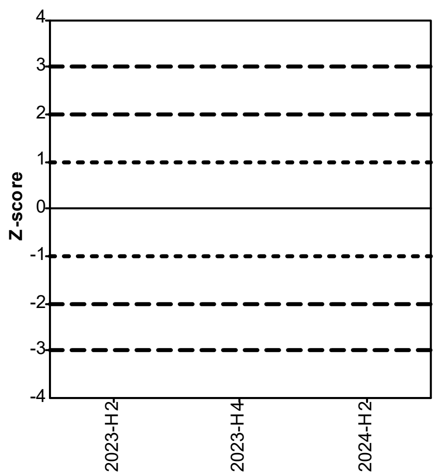


Instrument ID	

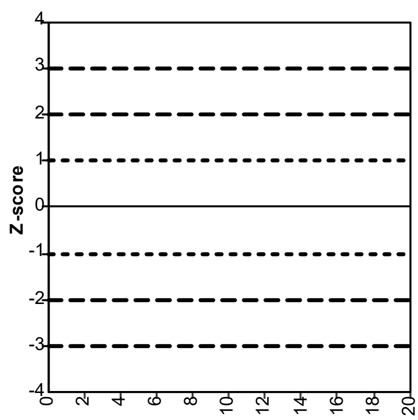
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor

Factor VIII Inhibitor (by assay concept)

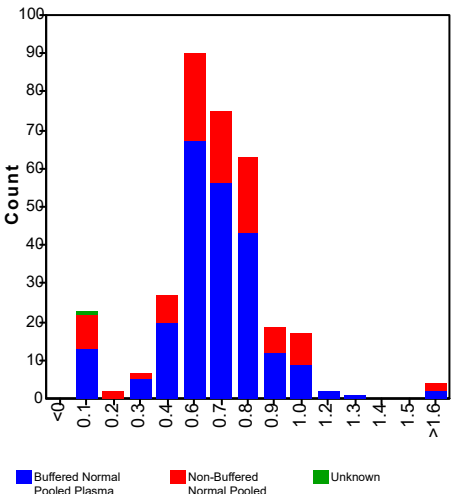
Sample No	24.115		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 0.7 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-January-2027		
Homogeneity	0.0 %	**Homogeneity Parameter**	FVIII inhibitor
Number of Participants	342		
Number of Responders	314	**Response Rate**	92 %
Comments	Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.		

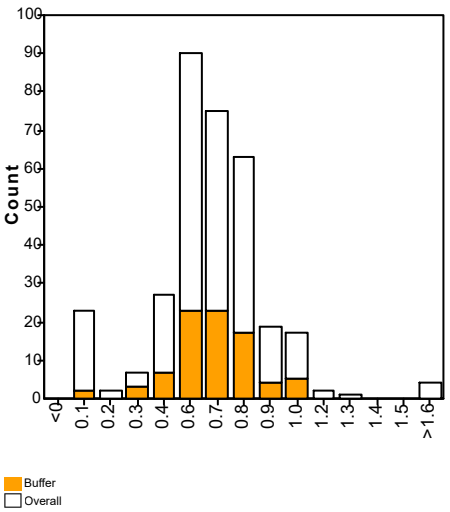
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	330	0.7	0.01	30.4	0.0 - 2.2	<0.6					
Buffered Normal Pooled Plasma	230	0.6	0.02	28.3	0.0 - 2.2	<0.6					
Buffer	84	0.7	0.02	27.9	0.0 - 1.1	<0.6					

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	330	0.7	0.01	30.4	0.0 - 2.2
Non-Buffered Normal Pooled Plasma	99	0.7	0.03	36.5	0.0 - 1.7
Buffer	59	0.7	0.04	31.8	0.0 - 1.7
Buffer + Albumin	2	0.8			0.5 - 1.1
Factor VIII Deficient Plasma	21	0.7	0.06	33.0	0.0 - 1.6
Heat-activated normal plasma	3	0.6			0.5 - 0.8
Other	10	0.5	0.15	73.9	0.0 - 1.0
Unknown	4	0.2			0.0 - 0.7
Buffered Normal Pooled Plasma	230	0.6	0.02	28.3	0.0 - 2.2
Buffer + Albumin	25	0.7	0.07	39.6	0.0 - 1.9
Factor VIII Deficient Plasma	94	0.6	0.02	28.4	0.0 - 2.2
Heat-inactivated normal plasma	15	0.6	0.05	27.3	0.0 - 0.8
Other	12	0.7	0.07	27.2	0.4 - 1.0
Unknown	1	0.0			-
Factor VIII Deficient Plasma	1	0.0			-





Factor VIII inhibitor | Factor VIII Inhibitor (by assay concept)

Sample No 24.116
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 2.6 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-January-2027
Homogeneity 1.6 % **Homogeneity Parameter** FVIII inhibitor
For any method used for the measurement of this parameter with a **CV ≤ 5.3%** 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 342
Number of Responders 314 **Response Rate** 92 %
Comments Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

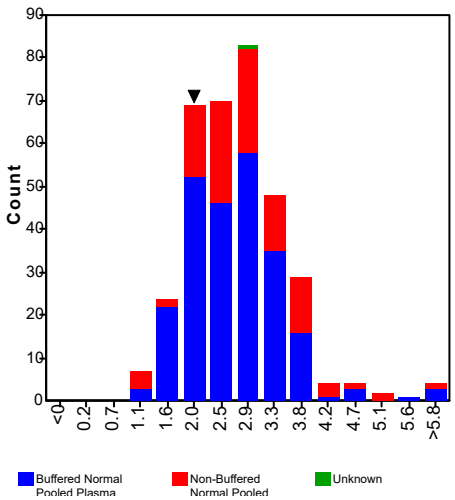
The following participant reported a deviating result which was excluded in the statistical evaluation:
3815 : 0 BU/mL

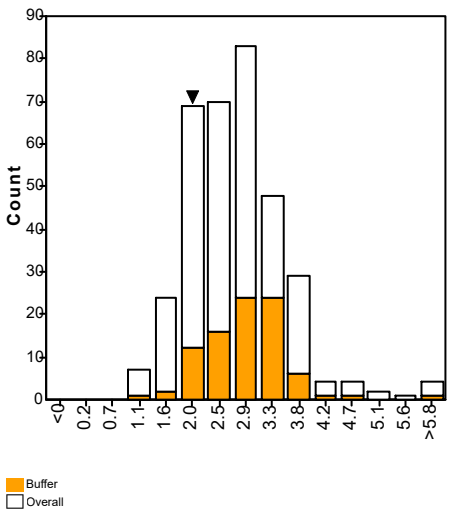
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	345	2.7	0.05	27.0	1.2 - 8.0	2.1	-0.82				
Buffered Normal Pooled Plasma	240	2.6	0.06	27.1	1.2 - 8.0	2.1	-0.75				
Buffer	88	2.9	0.08	21.2	1.3 - 7.6	2.1	-1.28				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	345	2.7	0.05	27.0	1.2 - 8.0
Non-Buffered Normal Pooled Plasma	104	2.8	0.09	26.5	1.2 - 5.9
Buffer	60	3.0	0.11	23.6	1.3 - 5.1
Buffer + Albumin	2	3.2			2.3 - 4.1
Factor VIII Deficient Plasma	22	2.5	0.17	24.5	1.7 - 5.9
Heat-activated normal plasma	3	2.7			2.5 - 3.6
Other	13	2.6	0.30	33.4	1.3 - 3.8
Unknown	4	1.9			1.2 - 3.6
Buffered Normal Pooled Plasma	240	2.6	0.06	27.1	1.2 - 8.0
Buffer + Albumin	26	2.8	0.24	35.0	1.7 - 8.0
Factor VIII Deficient Plasma	99	2.3	0.08	26.2	1.2 - 5.5
Heat-inactivated normal plasma	15	2.7	0.29	33.3	1.6 - 3.9
Other	12	3.0	0.26	23.6	1.7 - 4.0
Unknown	1	2.8			-
Factor VIII Deficient Plasma	1	2.8			-



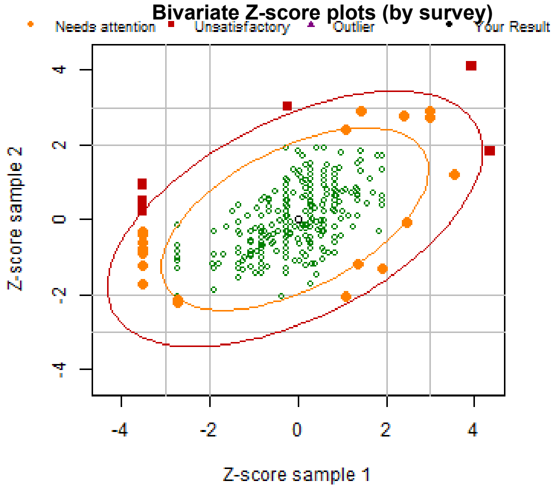


Factor VIII inhibitor

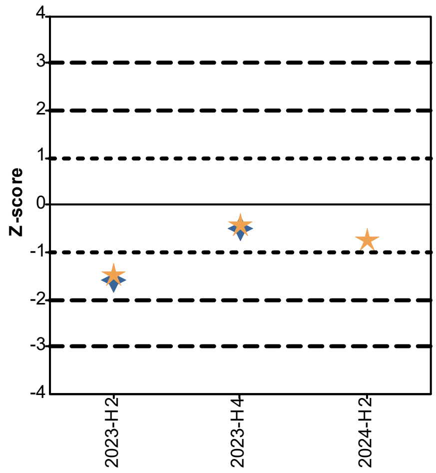
Factor VIII Inhibitor (by assay concept)

Instrument ID	

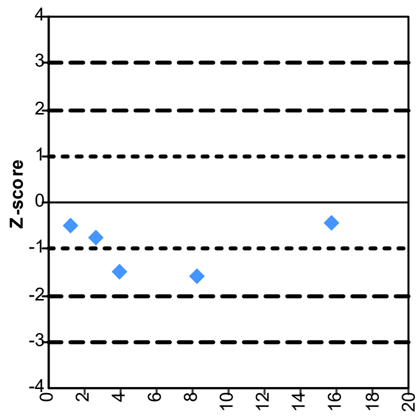
Bivariate Z-score plots (by survey)



Z-score history (by survey)

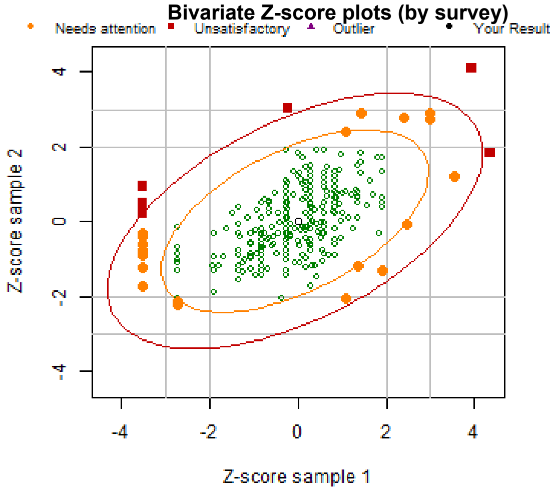


Z-score history (by consensus value)

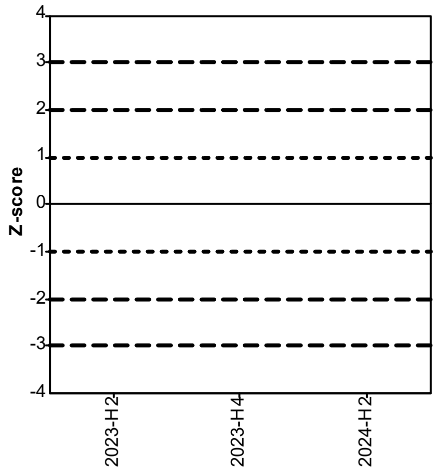


Instrument ID	

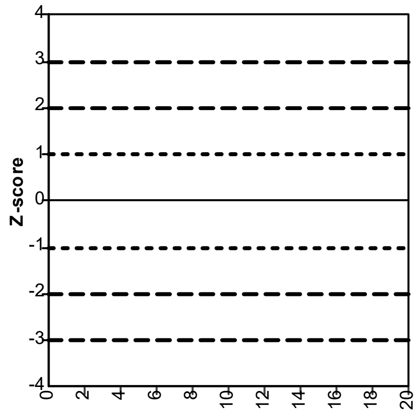
Bivariate Z-score plots (by survey)



Z-score history (by survey)

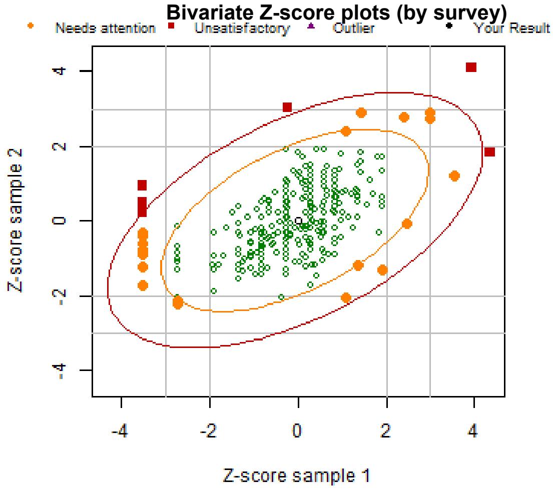


Z-score history (by consensus value)

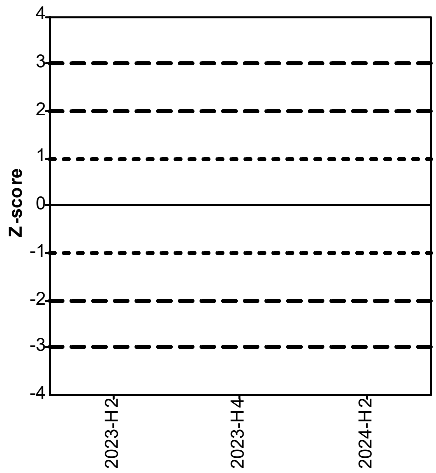


Instrument ID	

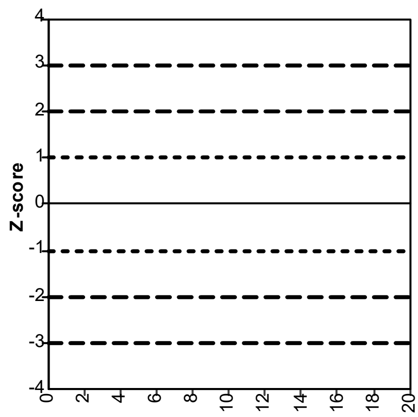
Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)



Factor VIII inhibitor

Factor VIII Inhibitor (by FVIII assay)

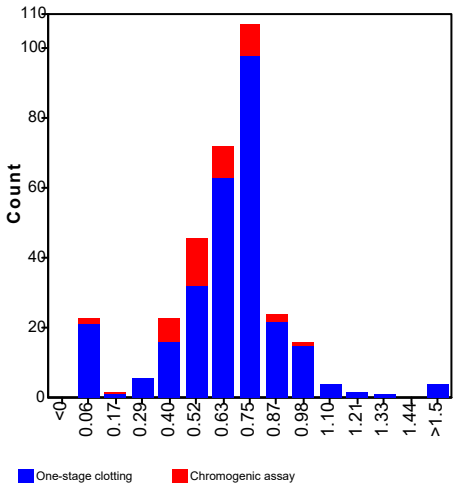
Sample No	24.115		
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 0.7 BU/mL		
Prior Use	None		
Unit	BU/mL		
Expiry Date	31-January-2027		
Homogeneity	0.0 %	**Homogeneity Parameter**	FVIII inhibitor
Number of Participants	342		
Number of Responders	314	**Response Rate**	92 %
Comments	Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.		

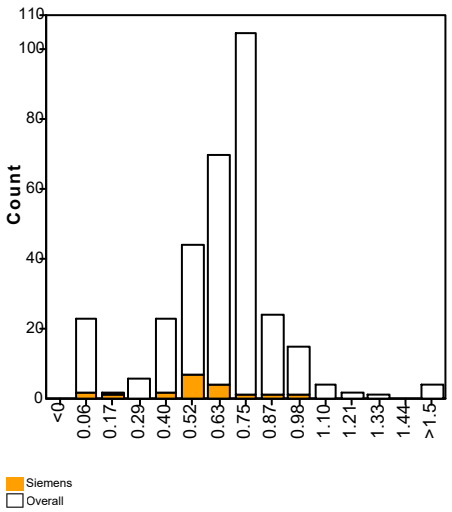
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	330	0.7	0.01	30.4	0.0 - 2.2	<0.6					
Chromogenic assay	45	0.6	0.03	30.1	0.0 - 1.0	<0.6					
Siemens Factor VIII	19	0.5	0.07	45.1	0.0 - 1.0	<0.6					

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	330	0.7	0.01	30.4	0.0 - 2.2
One-stage clotting assay	285	0.7	0.01	29.6	0.0 - 2.2
Hemoliance Synthasil APTT	1	0.8			-
Hyphen Biomed Cephen	2	0.4			0.0 - 0.9
Other	1	0.6			-
Roche APTT	2	0.3			0.0 - 0.5
Siemens Actin FS	48	0.6	0.03	28.5	0.0 - 1.3
Siemens Actin FSL	9	0.7			0.0 - 0.9
Siemens Pathromtin SL	35	0.7	0.06	41.4	0.0 - 1.7
Stago Cephalin/Kaolin/CK Prest	45	0.7	0.03	26.9	0.0 - 1.9
Stago PTT (automate)	14	0.6	0.17	81.0	0.0 - 2.2
Tcoag Automated APTT	1	0.8			-
Tcoag TriniClot APTT S	1	0.7			-
Tcoag TriniClot APTT-HS	2	0.5			0.4 - 0.6
Technoclone Dapttin	2	0.4			0.0 - 0.9
Werfen HemosIL APTT lyophilised silica	1	0.6			-
Werfen HemosIL APTT-SP liquid silica	4	0.7			0.5 - 0.8
Werfen HemosIL SynthASil	111	0.7	0.02	23.8	0.0 - 1.6
Chromogenic assay	45	0.6	0.03	30.1	0.0 - 1.0
Chromogenix Coamatic Factor VIII	11	0.6	0.07	30.0	0.4 - 0.9
Chromogenix Coatest SP Factor VIII	2	0.5			0.4 - 0.5
Hyphen Biomed Biophen Factor VIII	2	0.6			0.5 - 0.8
Other	2	0.7			0.5 - 0.8
Precision Biologic Cryocheck Chromog	6	0.6			0.4 - 0.7
TCoag Trinichrom FVIII	1	0.6			-
Technoclone Factor VIII	1	0.6			-





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

Sample No 24.116
Sample Details Plasma with a Factor VIII Inhibitor level of approx. 2.6 BU/mL
Prior Use None
Unit BU/mL
Expiry Date 31-January-2027
Homogeneity 1.6 % **Homogeneity Parameter** FVIII inhibitor
For any method used for the measurement of this parameter with a **CV ≤ 5.3%** 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 342
Number of Responders 314 **Response Rate** 92 %
Comments Participant **3828** submitted for three instruments the same results. The results of the second and third instrument were excluded in the statistical analysis.

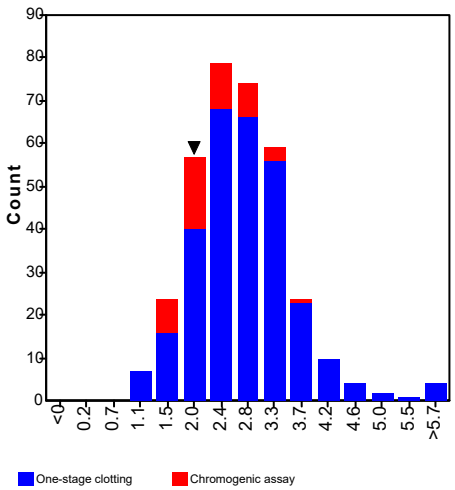
The following participant reported a deviating result which was excluded in the statistical evaluation:
3815 : 0 BU/mL

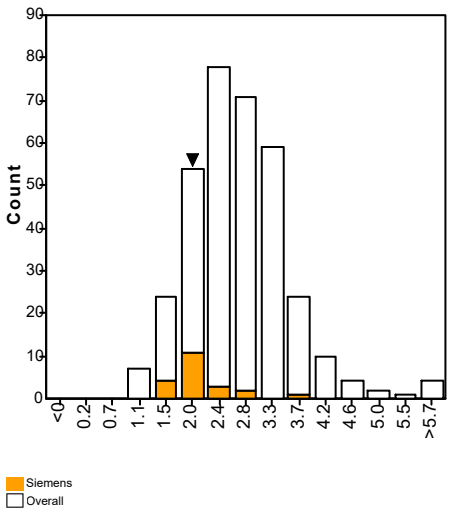
Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	345	2.7	0.05	27.0	1.2 - 8.0	2.1	-0.82				
Chromogenic assay	48	2.2	0.09	22.1	1.5 - 3.9	2.1	-0.26				
Siemens Factor VIII	21	2.1	0.09	16.8	1.5 - 3.9	2.1	0.08				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	345	2.7	0.05	27.0	1.2 - 8.0
One-stage clotting assay	297	2.8	0.05	26.1	1.2 - 8.0
Hemoliance Synthasil APTT	1	4.0			-
Hyphen Biomed Cephen	2	2.9			2.7 - 3.0
Other	1	3.2			-
Roche APTT	2	2.3			2.2 - 2.4
Siemens Actin FS	50	2.5	0.11	25.7	1.6 - 4.6
Siemens Actin FSL	9	2.7			2.1 - 3.6
Siemens Pathromtin SL	35	2.7	0.19	32.4	1.2 - 8.0
Stago Cephalin/Kaolin/CK Prest	48	2.7	0.09	18.0	1.3 - 7.6
Stago PTT (automate)	14	2.8	0.39	41.5	1.2 - 5.5
Tcoag Automated APTT	1	2.2			-
Tcoag TriniClot APTT S	1	2.7			-
Tcoag TriniClot APTT-HS	2	2.5			2.1 - 2.8
Technoclone Dapttin	2	2.9			2.9 - 3.0
Werfen HemosIL APTT lyophilised silica	1	4.0			-
Werfen HemosIL APTT-SP liquid silica	4	2.4			1.7 - 3.2
Werfen HemosIL SynthASil	118	3.0	0.08	24.7	1.2 - 5.9
Chromogenic assay	48	2.2	0.09	22.1	1.5 - 3.9
Chromogenix Coamatic Factor VIII	12	2.5	0.23	25.3	1.6 - 3.4
Chromogenix Coatest SP Factor VIII	2	1.7			1.6 - 1.8
Hyphen Biomed Biophen Factor VIII	2	2.0			1.7 - 2.3
Other	2	2.4			2.0 - 2.8
Precision Biologic Cryocheck Chromog	6	2.2			1.7 - 3.2
TCoag Trinichrom FVIII	1	2.4			-
Technoclone Factor VIII	1	2.9			-



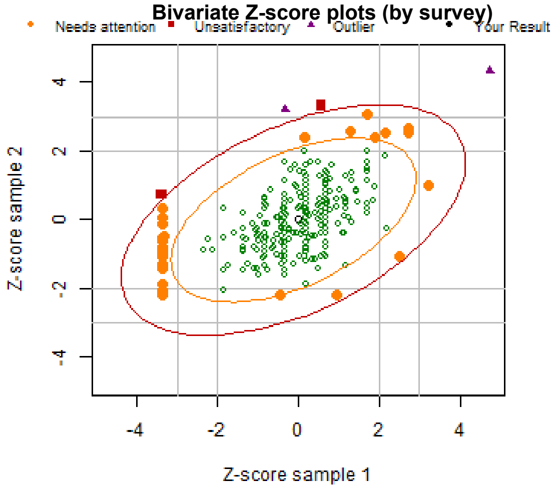


Factor VIII inhibitor

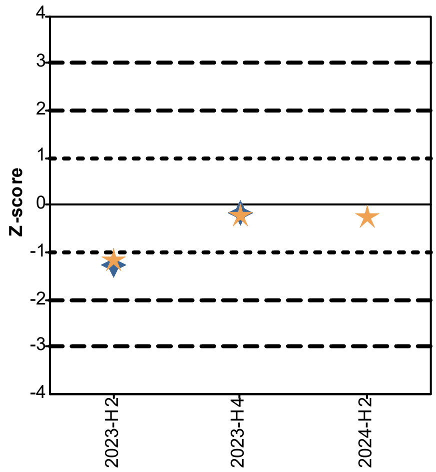
Factor VIII Inhibitor (by FVIII assay)

Instrument ID	

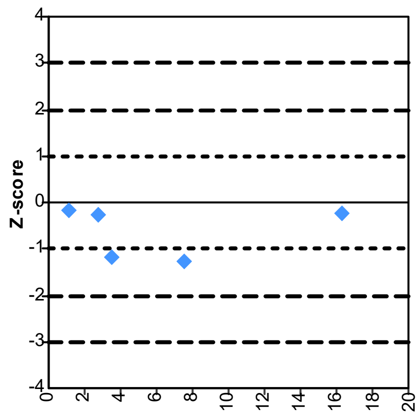
Bivariate Z-score plots (by survey)



Z-score history (by survey)

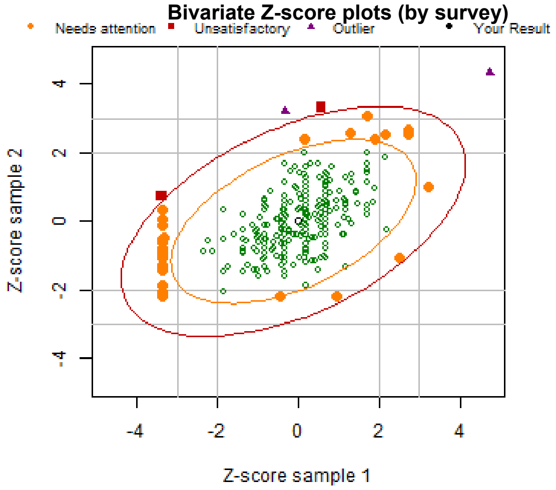


Z-score history (by consensus value)

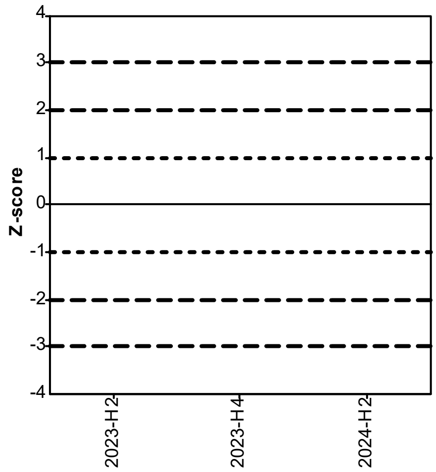


Instrument ID	

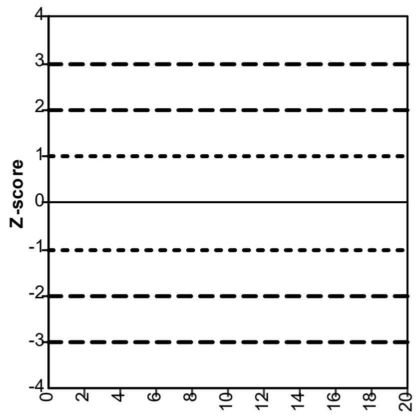
Bivariate Z-score plots (by survey)



Z-score history (by survey)

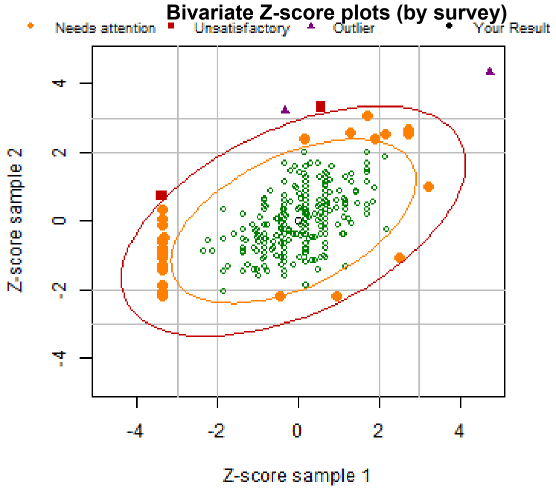


Z-score history (by consensus value)

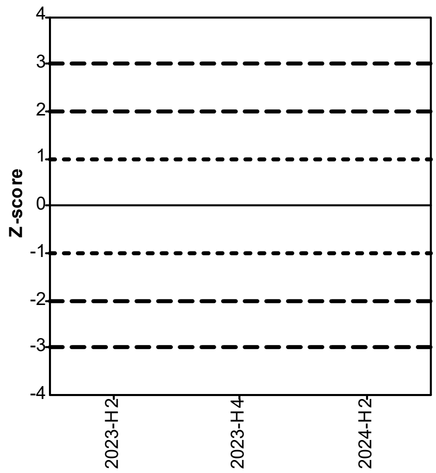


Instrument ID	

Bivariate Z-score plots (by survey)



Z-score history (by survey)



Z-score history (by consensus value)