

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2020-M3

Main

Labcode 99906936

Date of Issue : 30-October-2020

Survey : 2020-M3

Report : Main

Note:

In the Survey Manual 2020 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2020 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 on page 21 of the Survey Manual.

General Information

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **December 8th, 2020**. 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 .

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Appendices are an integral part of the total report.

OVERVIEW Z-SCORES



Satisfactory ($-2 \leq Z\text{-score} \leq 2$)



Need attention ($-3 < Z\text{-score} < -2$ or $2 < Z\text{-score} < 3$)



Unsatisfactory ($Z\text{-score} \leq -3$ or ≥ 3)

Module	Parameter	Sample	Test System	Total	Assay	Method
Factor IX Inhibitor	Factor IX Inhibitor	20.149	1	-0.31	-0.40	-0.41
		20.150	1	1.07	1.21	1.12

Factor IX Inhibitor	Factor IX Inhibitor
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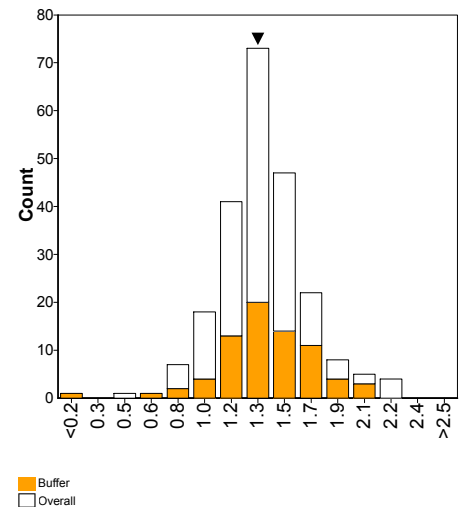
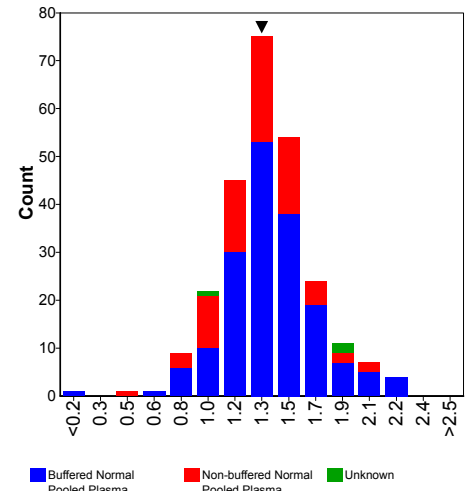
Sample No	20.149	
Sample Details	Plasma with a Factor IX Inhibitor level of approx. 1 BU/mL	
Prior Use	Prior Use: None	
Unit	Units:	
Expiry Date	28-February-2023	
Homogeneity	0.0 %	Homogeneity Parameter FIX inhibitor
Number of Participants	263	
Number of Responders	243	Response Rate 92 %
Comments	The following participants reported deviating results which were excluded in the statistical evaluation:	
	203	: 92.94
	9907169	: 16

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	254	1.4	0.02	19.8	0.0 - 2.3	1.3	-0.31				
Buffered Normal Pooled Plasma	174	1.4	0.03	18.8	0.0 - 2.3	1.3	-0.40				
Buffer	73	1.4	0.04	19.9	0.0 - 2.0	1.3	-0.41				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	254	1.4	0.02	19.8	0.0 - 2.3
Unknown	3	1.9			1.0 - 1.9
Buffer	2	1.9			1.9 - 1.9
Factor IX deficient plasma	1	1.0			-
Buffered Normal Pooled Plasma	174	1.4	0.03	18.8	0.0 - 2.3
Buffer + Albumin	22	1.5	0.07	16.6	1.0 - 2.2
Factor IX deficient plasma	63	1.4	0.04	16.8	0.8 - 2.3
Heat-inactivated normal plasma	7	1.6			1.1 - 1.7
Other	7	1.3			0.8 - 1.6
Unknown	2	1.4			0.8 - 2.0
Non-buffered Normal Pooled Plasma	77	1.3	0.04	20.4	0.4 - 2.1
Buffer	43	1.3	0.05	19.1	0.4 - 2.1
Buffer + Albumin	3	1.6			1.0 - 1.8
Factor IX deficient plasma	15	1.3	0.09	21.2	0.8 - 1.8
Heat-inactivated normal plasma	3	1.6			1.4 - 2.0
Other	12	1.2	0.09	20.2	0.9 - 1.5
Unknown	1	1.0			-



Factor IX Inhibitor	Factor IX Inhibitor
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Sample No 20.150
Sample Details Plasma with a Factor IX Inhibitor level of approx. 19 BU/mL
Prior Use Prior Use: None
Unit Units:
Expiry Date 28-February-2023
Homogeneity 3.7 % **Homogeneity Parameter** FIX inhibitor
 For any method used for the measurement of this parameter with a **CV ≤ 12.3%** 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.

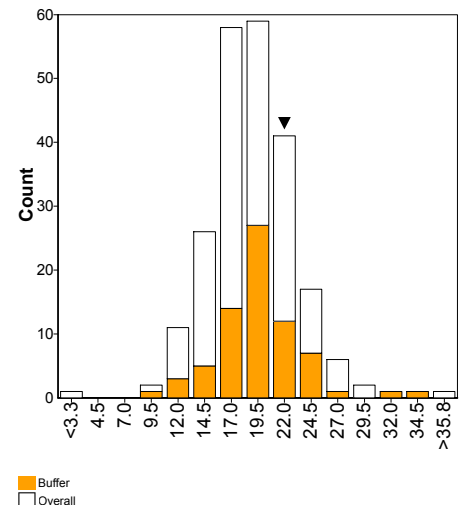
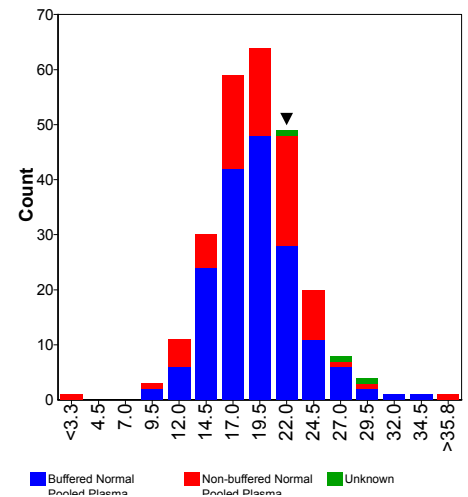
Number of Participants 263
Number of Responders 243 **Response Rate** 92 %
Comments The following participants reported deviating results which were excluded in the statistical evaluation:
203 : 258
271 : <0.40
1009 : 2.000
5088 : 230
9907169 : 2

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	252	19.2	0.30	19.7	3.0 - 36.1	23.2	1.07				
Buffered Normal Pooled Plasma	171	18.9	0.34	18.8	9.9 - 33.9	23.2	1.21				
Buffer	72	19.5	0.48	16.8	9.9 - 33.9	23.2	1.12				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	252	19.2	0.30	19.7	3.0 - 36.1
Unknown	3	27.4			20.8 - 28.3
Buffer	2	27.8			27.4 - 28.3
Factor IX deficient plasma	1	20.8			-
Buffered Normal Pooled Plasma	171	18.9	0.34	18.8	9.9 - 33.9
Buffer + Albumin	22	18.0	1.04	21.7	12.6 - 25.0
Factor IX deficient plasma	61	18.5	0.51	17.4	13.0 - 30.8
Heat-inactivated normal plasma	6	16.7			10.0 - 28.6
Other	8	20.2			14.2 - 28.0
Unknown	2	17.0			15.3 - 18.6
Non-buffered Normal Pooled Plasma	78	19.5	0.57	20.7	3.0 - 36.1
Buffer	44	19.6	0.64	17.4	10.5 - 36.1
Buffer + Albumin	3	22.9			21.2 - 24.2
Factor IX deficient plasma	15	19.1	1.41	22.9	3.0 - 25.3
Heat-inactivated normal plasma	3	23.0			23.0 - 25.6
Other	12	17.7	1.69	26.4	12.7 - 30.4
Unknown	1	20.0			-

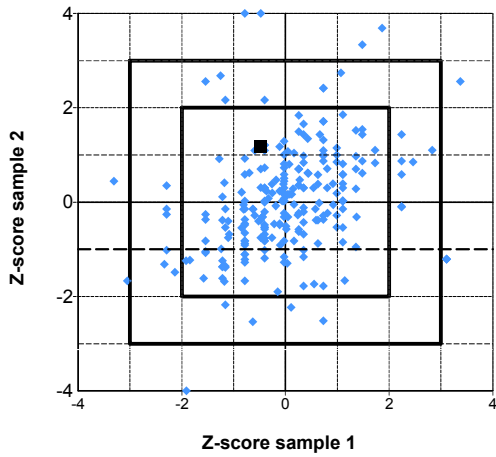


Factor IX Inhibitor

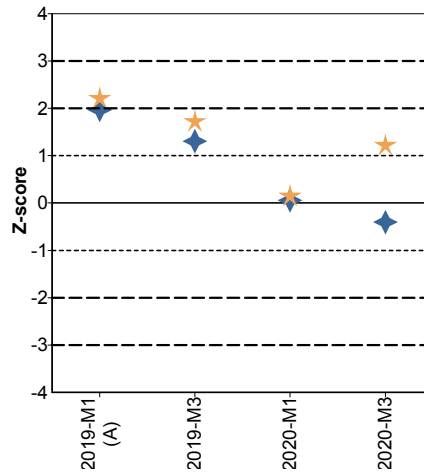
Factor IX Inhibitor

Instrument ID

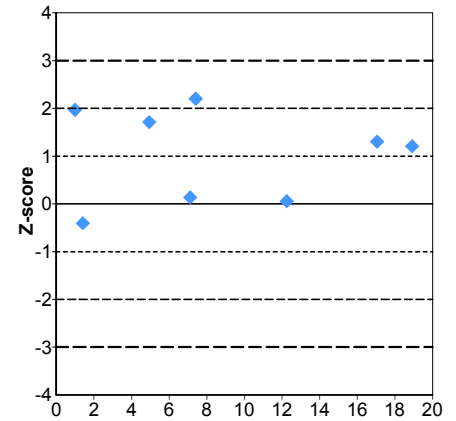
Z-score plot



Z-score history (by survey)

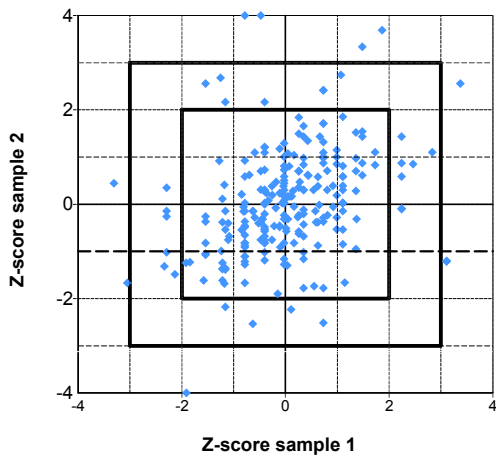


Z-score history (by consensus value)

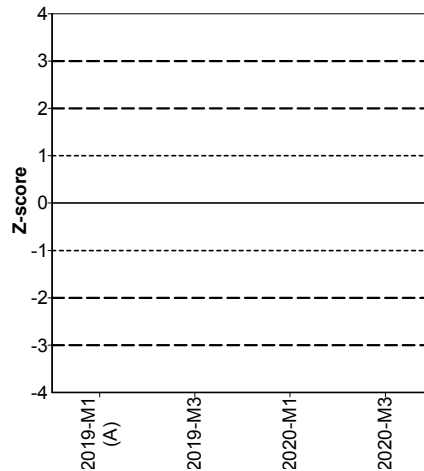


Instrument ID

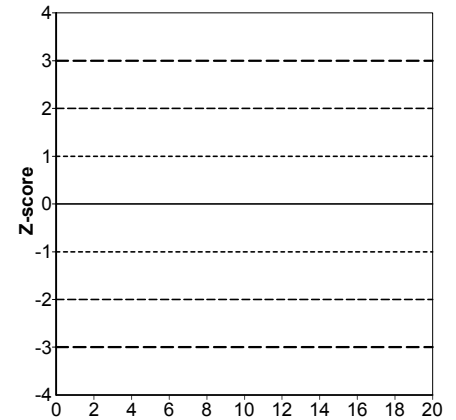
Z-score plot



Z-score history (by survey)

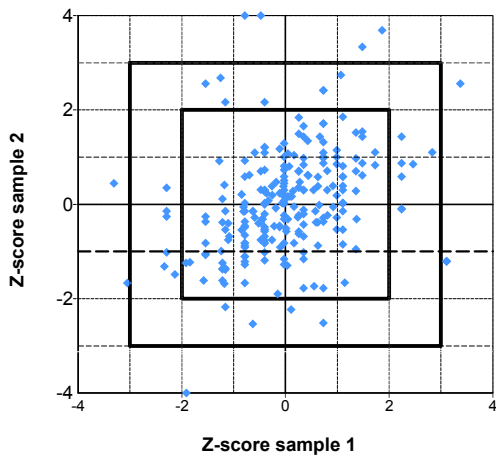


Z-score history (by consensus value)

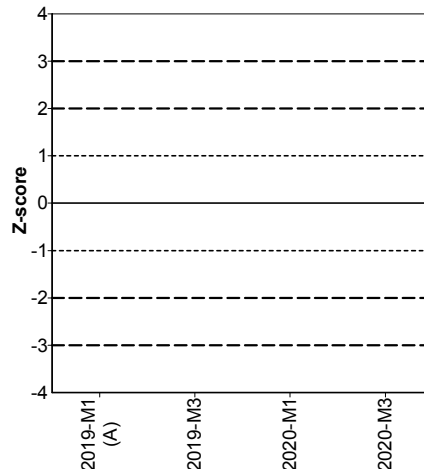


Instrument ID

Z-score plot



Z-score history (by survey)



Z-score history (by consensus value)

