

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2020-M2

Main

Labcode 99906936

Date of Issue : 07-August-2020

Survey : 2020-M2

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 **September 18th, 2020**.

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

Exclusion of results

Results < [value] or > [value] are excluded from the statistical analysis.

When other 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 two or three times the same results, suggesting that this are separate results.

Only results clearly marked with different instruments or different methods are included as additional result. Duplicated results, which are probably **no** separate results are excluded in the statistical analysis. We have excluded the results from the second and third test system in the statistical analysis from the following participants: **887, 3841, 9907150, 99900242**.

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

This report is authorized by:

Dr. P. Meijer
Director

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 ($-3 \leq Z\text{-score} < -2$ or $2 < Z\text{-score} \leq 3$)
 Unsatisfactory ($Z\text{-score} < -3$ or > 3)

Module	Parameter	Sample	Test System	Total	Assay	Method
Factor VIII inhibitor	Factor VIII Inhibitor	20.97	1	-1.82	-1.64	-1.61

Factor VIII inhibitor	Factor VIII Inhibitor
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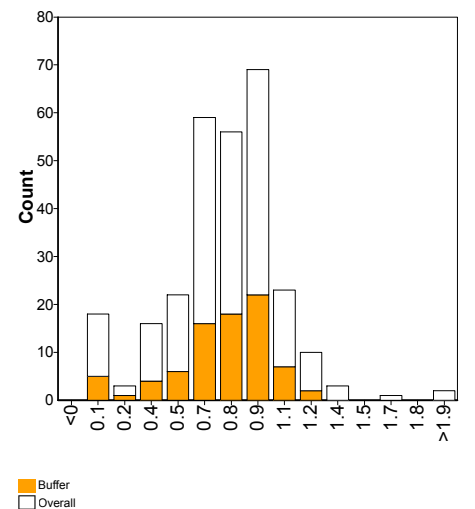
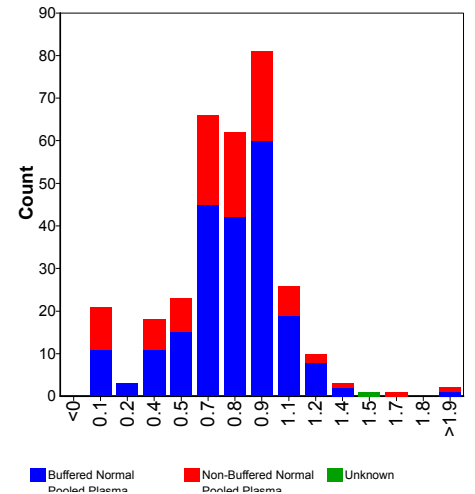
Sample No	20.96	Homogeneity Parameter	FVIII inhibitor
Sample Details	Plasma with a Factor VIII Inhibitor level of approx. 0.9 BU/mL	Response Rate	95 %
Prior Use	Prior Use: None		
Unit	Units: BU/mL		
Expiry Date	28-February-2023		
Homogeneity	0.0 %		
Number of Participants	346		
Number of Responders	330		
Comments	None		

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range	your result	z-score	your result	z-score	your result	z-score
Total Group	317	0.8	0.02	33.5	0.0 - 5.0	<0.6					
Buffered Normal Pooled Plasma	217	0.8	0.02	31.6	0.0 - 5.0	<0.6					
Buffer	81	0.8	0.03	30.6	0.0 - 1.2	<0.6					

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	317	0.8	0.02	33.5	0.0 - 5.0
Non-Buffered Normal Pooled Plasma	99	0.7	0.04	37.7	0.0 - 1.9
Buffer	61	0.8	0.04	35.3	0.0 - 1.7
Buffer + Albumin	2	0.8			0.7 - 0.8
Factor VIII Deficient Plasma	15	0.8	0.11	43.2	0.0 - 1.9
Heat-activated normal plasma	4	0.8			0.6 - 1.0
Other	15	0.6	0.14	73.2	0.0 - 1.4
Unknown	2	0.3			0.0 - 0.6
Buffered Normal Pooled Plasma	217	0.8	0.02	31.6	0.0 - 5.0
Buffer + Albumin	19	0.7	0.08	37.4	0.0 - 1.2
Factor VIII Deficient Plasma	91	0.8	0.03	31.4	0.0 - 5.0
Heat-inactivated normal plasma	14	0.9	0.07	23.2	0.4 - 1.1
Other	10	0.6	0.18	71.5	0.0 - 1.1
Unknown	2	1.0			0.9 - 1.0
Unknown	1	1.5			-
Unknown	1	1.5			-



Factor VIII inhibitor	Factor VIII Inhibitor
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Sample No 20.97

Sample Details Plasma with a Factor VIII Inhibitor level of approx. 13 BU/mL

Prior Use Prior Use: None

Unit Units: BU/mL

Expiry Date 28-February-2023

Homogeneity 3.7 % **Homogeneity Parameter** FVIII 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 346

Number of Responders 330 **Response Rate** 95 %

Comments The following participants reported a deviating result which were excluded in the statistical evaluation:

1132 : 0.0 BU/mL

3849 : 0.0 BU/mL

3858 : 1.2 BU/mL

9060 : 0.7 BU/mL

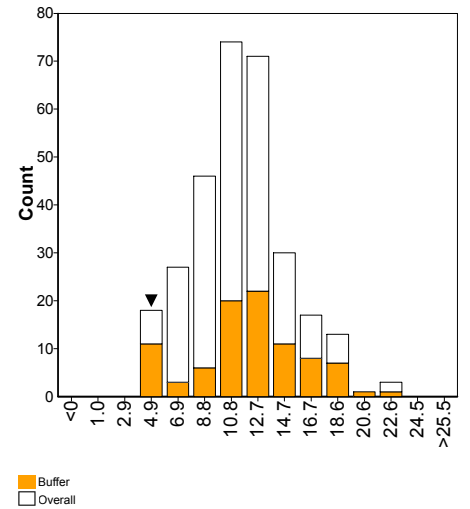
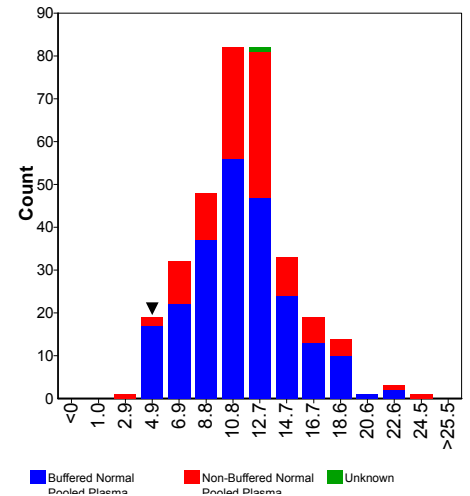
99905866 : 1.05 BU/mL

Own Reagent

	n	assigned value	Uncert.	CV (%)	Range						
						your result	z-score	your result	z-score	your result	z-score
Total Group	335	11.3	0.23	29.7	3.0 - 25.0	5.2	-1.82				
Buffered Normal Pooled Plasma	229	11.1	0.30	32.4	4.3 - 23.0	5.2	-1.64				
Buffer	90	12.0	0.56	35.3	4.8 - 21.8	5.2	-1.61				

Other Reagents

	n	assigned value	Uncert.	CV (%)	Range
Total Group	335	11.3	0.23	29.7	3.0 - 25.0
Non-Buffered Normal Pooled Plasma	105	11.7	0.35	24.8	3.0 - 25.0
Buffer	64	11.9	0.39	21.0	4.0 - 18.5
Buffer + Albumin	2	9.8			7.5 - 12.0
Factor VIII Deficient Plasma	17	11.3	1.15	33.7	7.2 - 22.2
Heat-activated normal plasma	4	11.6			10.0 - 16.0
Other	16	11.9	0.76	20.4	3.0 - 25.0
Unknown	2	7.8			6.6 - 9.0
Buffered Normal Pooled Plasma	229	11.1	0.30	32.4	4.3 - 23.0
Buffer + Albumin	19	11.6	0.65	19.7	8.0 - 16.0
Factor VIII Deficient Plasma	94	10.2	0.39	29.4	4.3 - 23.0
Heat-inactivated normal plasma	16	10.9	1.16	33.8	5.5 - 18.0
Other	9	10.0			5.9 - 15.0
Unknown	1	16.0			-
Unknown	1	12.0			-
Unknown	1	12.0			-

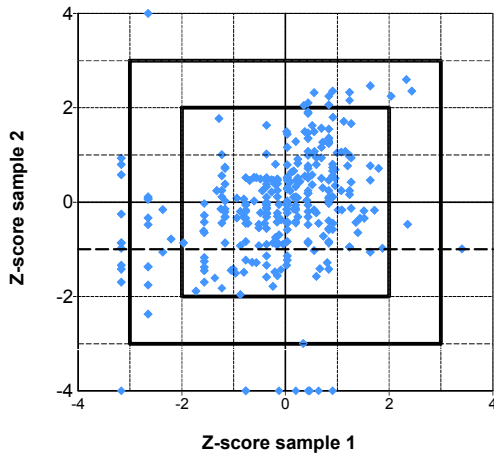


Factor VIII inhibitor

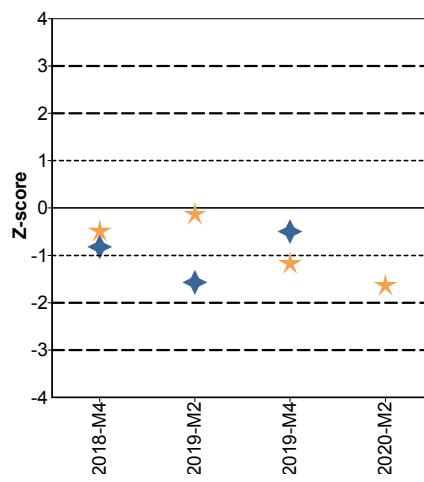
Factor VIII Inhibitor

Instrument ID

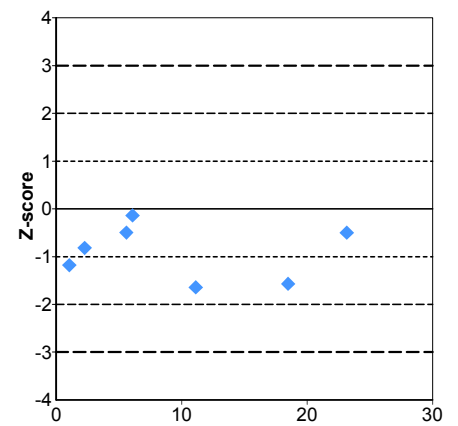
Z-score plot



Z-score history (by survey)

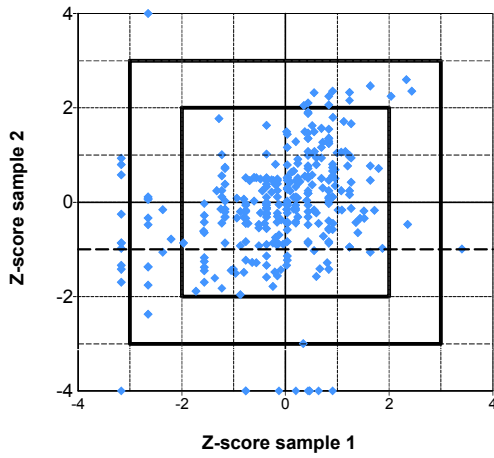


Z-score history (by consensus value)

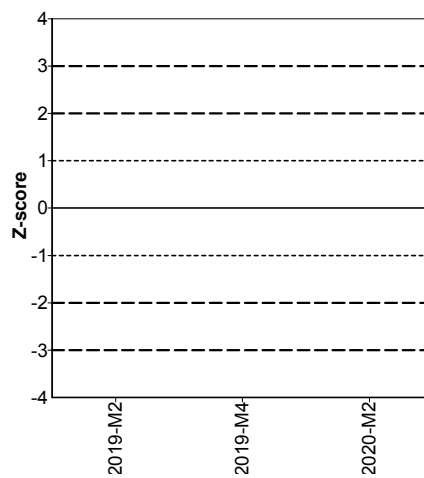


Instrument ID

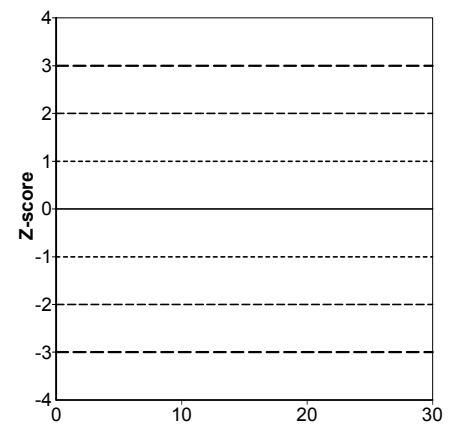
Z-score plot



Z-score history (by survey)

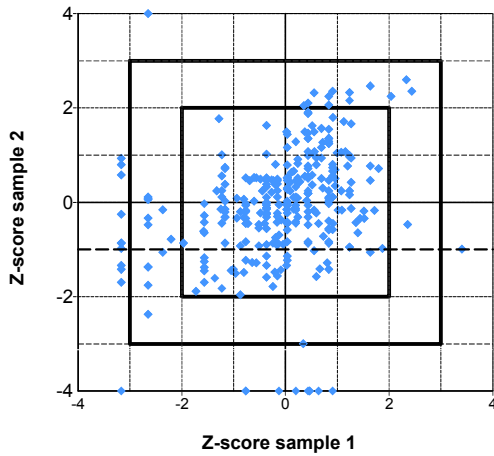


Z-score history (by consensus value)

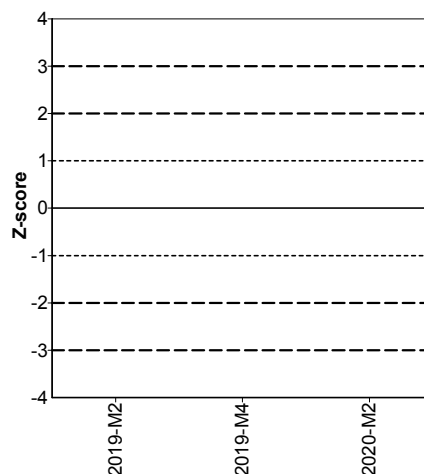


Instrument ID

Z-score plot



Z-score history (by survey)



Z-score history (by consensus value)

