

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-P2

PFA 100/200

Labcode 1492

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Date of Issue : 25-July-2022

Survey : 2022-P2

Report : PFA 100/200

Note:

In the Survey Manual 2022 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2022 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 5th, 2022**.

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

Exclusion of results

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

When other results are excluded in the statistical analysis, these results are placed between brackets.

Several participants reported comments in numeric result fields (e.g. an error code of the PFA analyser). These comments are placed between brackets. Because of the limited space for "your results" in the report, these comments are not always fully visible.

Report results in correct units

Several participants reported haematocrit in percentage. Please use in future surveys for haematocrit the unit: L/L. We have now corrected the values to this unit.

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 .

ECAT Foundation

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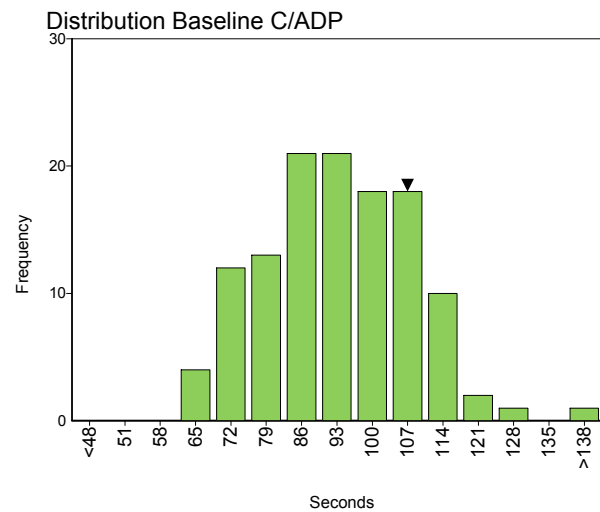
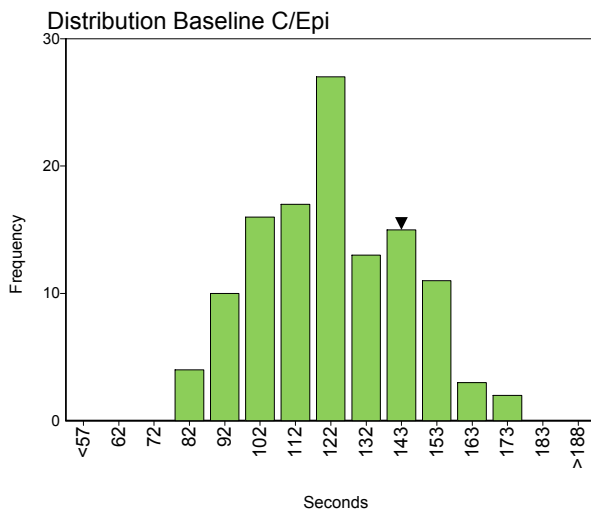
Appendices are an integral part of the total report.

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Baseline results from donor native blood:

Test Parameter	Unit	n	Mean	Range	Own Result	Own Result	Own Result
Platelet Count	x10 ⁹ /L	107	257	121 - 431	212		
Mean Platelet Volume	fL	92	9.7	7.6 - 12.0	10.3		
Haematocrit	L/L	103	0.41	0.34 - 0.51	0.38		
VWF:AG	%	41	116	62 - 219			
VWF:RCo	%	11	99	57 - 164			
VWF:Activity	%	32	124	58 - 231			
VWF:CBA	%	8	95	49 - 199			
FVIII:C	%	33	131	57 - 218			
Baseline C/Epi	seconds	118	122	79 - 174	147		
Baseline C/ADP	seconds	121	93	63 - 142	107		



Classification baseline results from donor native blood:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
					Own Result	Own Result	Own Result
Platelet Count	105	1	1	0	Normal		
Mean Platelet Volume	88	3	2	1	Normal		
Haematocrit	98	4	1	1	Normal		
VWF:AG	39	0	2	0			
VWF:RCo	11	0	0	0			
VWF:Activity	30	0	1	2			
VWF:CBA	6	1	1	1			
FVIII:C	33	0	2	2			
Baseline C/Epi	115	4	0	0	Normal		
Baseline C/ADP	113	8	0	0	Normal		

Comments:

On the basis of the baseline test results reported by all participants, it can be concluded that almost in all cases a normal donor was used.

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Sample No 22.132
Sample Details PFA sample with a severe defect
Prior Use None
Unit seconds
Expiry Date 21-April-2024
Homogeneity 2.8 % **Homogeneity Parameter** C/ADP
 For any method used for the measurement of this parameter with a **CV ≤ 9.3%** 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 154
Number of Responders 134 **Response Rate** 87 %

Comments A number of participants reported error codes for the measurement with the C/Epi and/or C/ADP cartridge.
 Furthermore, a substantial number of participants reported a results above the upper limit of the measuring range [$>$ (value)] for the C/Epi and/or C/ADP cartridge.

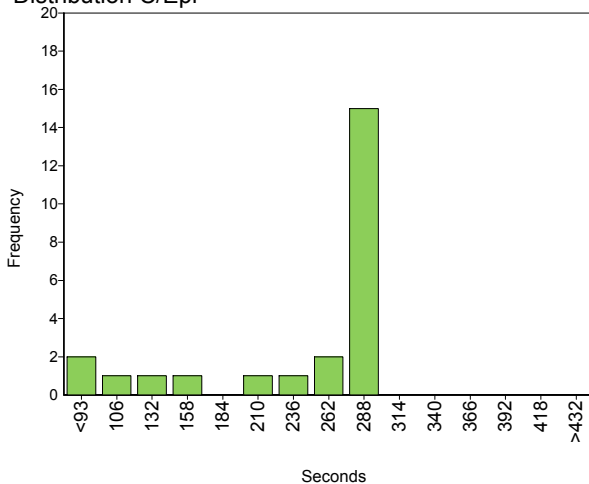
Classification for sample 22.132:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
					Abnormal		
C/Epi	3	0	119	6	Abnormal		
C/ADP	4	1	115	8	Abnormal		

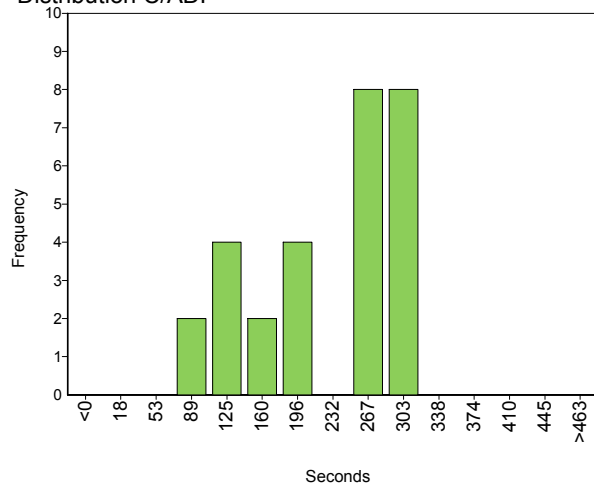
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	24	262	14.4	21.5	59 - 300	>300					
C/ADP	28	229	18.5	34.2	80 - 300	>300					

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	0
Borderline	0
Mild Defect	2
Severe Defect	102
Aspirin-like Defect	2
Unable to Interpret	8
Test Failure	14
Other	3
No Conclusion	4

Severe Defect		
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Conclusion Comments:

Most of the participants reported a severe defect in this sample. There were also a number of participants that observed a test failure or were not able to interpret the results.

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Sample No	22.133		
Sample Details	PFA normal control		
Prior Use	None		
Unit	seconds		
Expiry Date	21-April-2024		
Homogeneity	-	Homogeneity Parameter	n.a.
Number of Participants	154		
Number of Responders	134	Response Rate	87 %
Comments	<p>A few participants reported error codes for the measurement with the C/Epi and/or C/ADP cartridge.</p> <p>Furthermore, two participants reported a results above the upper limit of the measuring range [> (value)] for the C/Epi.</p>		

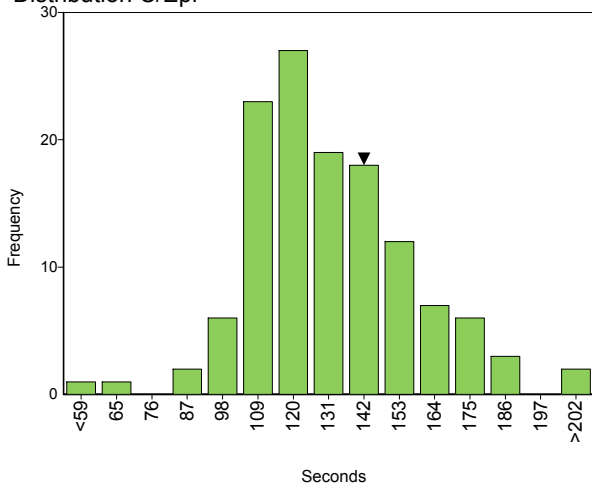
Classification for sample 22.133:

Test Parameter	Normal	Borderine	Abnormal	No Classification			
					Own Result	Own Result	Own Result
C/Epi	102	13	13	3	Normal		
C/ADP	109	14	10	2	Normal		

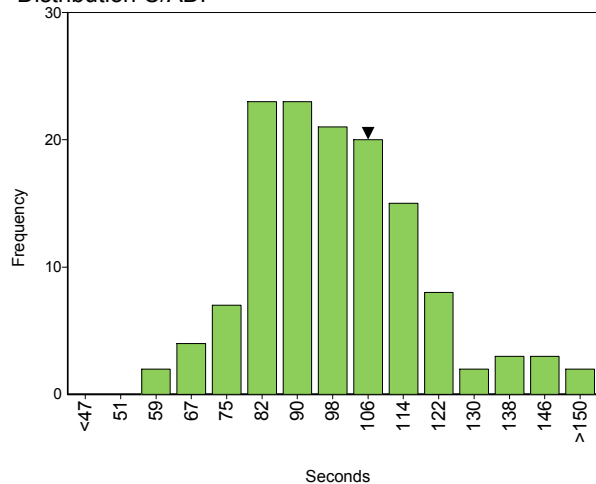
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range						
						your result	z-score	your result	z-score	your result	z-score
C/Epi	127	131	2.6	18.2	51 - 225	142	0.48				
C/ADP	133	98	1.9	17.4	59 - 196	105	0.40				

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	101
Borderline	14
Mild Defect	6
Severe Defect	1
Aspirin-like Defect	7
Unable to Interpret	1
Test Failure	3
Other	0
No Conclusion	2

Normal		

Conclusion Comments:

About 73% of the participants classified this sample correctly as normal. Surprisingly, about 10% of the participants observed a defect in this sample. There were also some participants that observed a test failure or were not able to interpret the results.