

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-P4

PFA 100/200

Labcode 1492

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Date of Issue : 12-January-2023

Survey : 2022-P4

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 **March 7th, 2023**.

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 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 .

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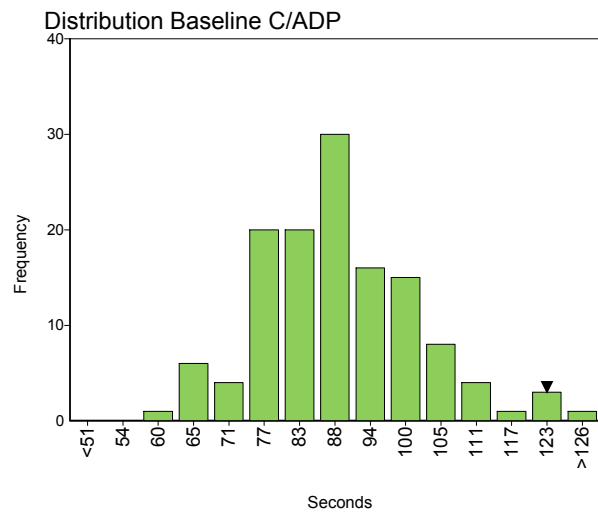
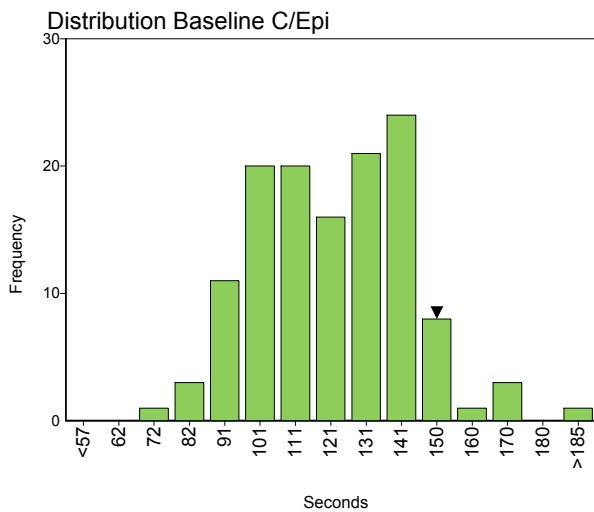
Appendices are an integral part of the total report.

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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	111	248	149 - 457	308		
Mean Platelet Volume	fL	98	9.9	6.9 - 14.2	8.7		
Haematocrit	L/L	111	0.41	0.33 - 0.52	0.42		
VWF:AG	%	49	111	54 - 215			
VWF:RCo	%	21	101	69 - 185			
VWF:Activity	%	33	115	60 - 194			
VWF:CBA	%	9	95	77 - 116			
FVIII:C	%	45	134	75 - 264			
Baseline C/Epi	seconds	129	121	70 - 210	149		
Baseline C/ADP	seconds	129	88	62 - 131	123		



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	112	2	0	1	Normal		
Mean Platelet Volume	88	4	6	2	Normal		
Haematocrit	107	3	2	0	Normal		
VWF:AG	47	1	1	0			
VWF:RCo	20	0	1	0			
VWF:Activity	33	0	0	0			
VWF:CBA	9	0	0	0			
FVIII:C	38	2	4	1			
Baseline C/Epi	127	2	0	1	Normal		
Baseline C/ADP	126	4	0	0	Normal		

Comments:

The following participants reported deviating results which were excluded in the statistical evaluation:

- 110 - (Platelet Count) : 220.000 x 10⁹/L
- 1024 - (Haematocrit) : 416 L/L
- 1172 - (Mean Platelet Volume) : 90.6 fL
- 1352 - (Platelet Count) : 320.000 x 10⁹/L
- 4501 - (Mean Platelet Volume) : 95.2 fL

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 22.233
Sample Details Normal PFA sample
Prior Use None
Unit seconds
Expiry Date 26-August-2022
Homogeneity -
Number of Participants 157
Number of Responders 141
Comments Two participants reported error codes for the measurement with the C/Epi cartridge. Furthermore, three participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi and/or C/ADP cartridge.

Homogeneity Parameter -

Response Rate 90 %

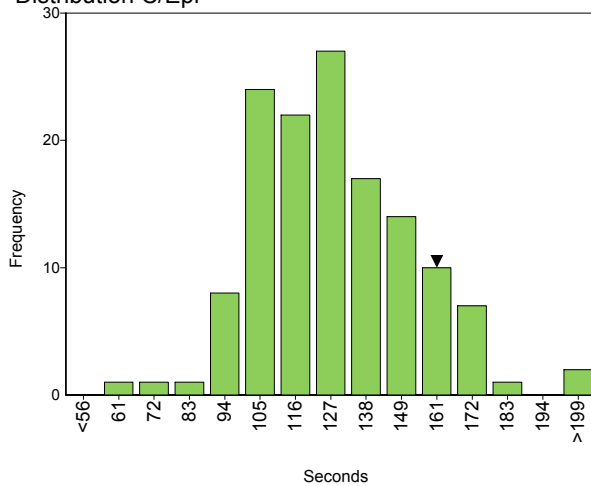
Classification for sample 22.233:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	117	6	14	1	Borderline		
C/ADP	103	13	19	1	Borderline		

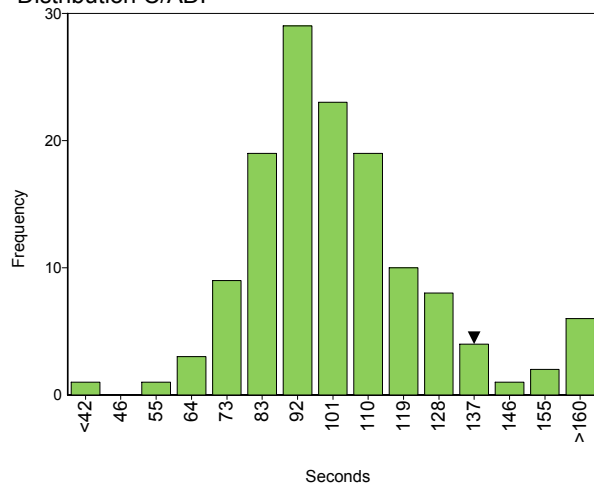
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	136	127	2.6	18.8	56 - 202	163	1.49				
C/ADP	136	101	2.1	19.5	33 - 295	136	1.79				

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	104
Borderline	14
Mild Defect	8
Severe Defect	1
Aspirin-like Defect	5
Unable to Interpret	3
Test Failure	5
Other	2
No Conclusion	2

Borderline		
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Conclusion Comments:

About 78% of the participants correctly classified this sample as normal. Surprisingly, about 10% of the participants observed a defect in this sample and also about 10% of the participant classified the sample as borderline. There were also some participants that observed a test failure or were not able to interpret the results or did not give a conclusion.

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Sample No 22.234
Sample Details PFA sample with a mild defect
Prior Use None
Unit seconds
Expiry Date 26-August-2022
Homogeneity 19.7 % **Homogeneity Parameter** C/Epi
 For any method used for the measurement of this parameter with a **CV ≤ 65.7%** 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 157
Number of Responders 141 **Response Rate** 90 %

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.

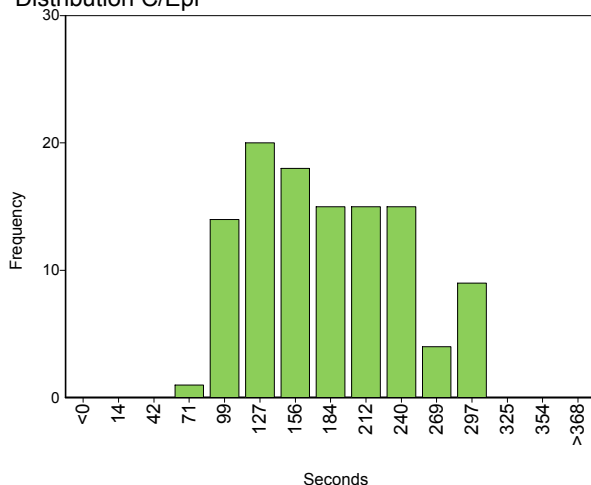
Classification for sample 22.234:

Test Parameter	Normal	Borderline	Abnormal	No Classification	Own Result	Own Result	Own Result
					Abnormal		
C/Epi	39	9	88	3	Abnormal		
C/ADP	30	4	102	5	Abnormal		

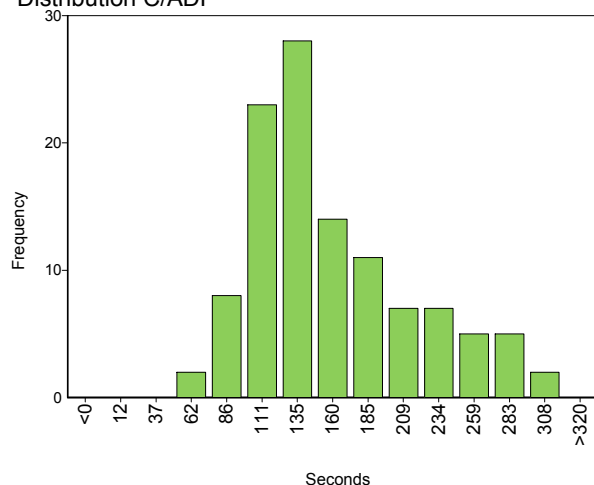
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	111	180	7.4	34.8	66 - 300	>300					
C/ADP	113	153	6.5	36.2	65 - 300	>300					

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	20
Borderline	4
Mild Defect	27
Severe Defect	53
Aspirin-like Defect	13
Unable to Interpret	7
Test Failure	6
Other	7
No Conclusion	7

Severe Defect		
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Conclusion Comments:

The sample distributed was intended to demonstrate results according to a mild defect. However, a heterogeneous pattern in the final conclusion was observed. From the participants who gave a final conclusion about 23% reported a mild defect, 45% reported a severe defect and 11% reported an aspirin-like defect. In addition, 17% of participants reported this sample to be normal. There were also several participants that observed a test failure or were not able to interpret the results or did not give a conclusion.

