

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-P2

PFA 100/200

Labcode 1492

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Date of Issue : 01-augustus-2023

Survey : 2023-P2

Report : PFA 100/200

Note:

In the Survey Manual 2023 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2023 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 22nd, 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 converted the values into 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

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
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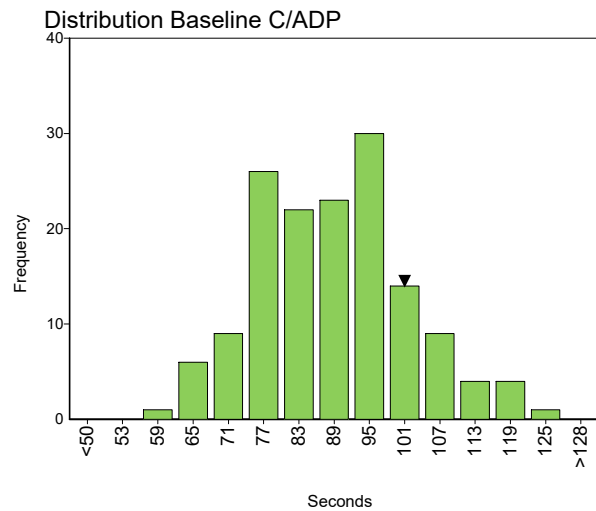
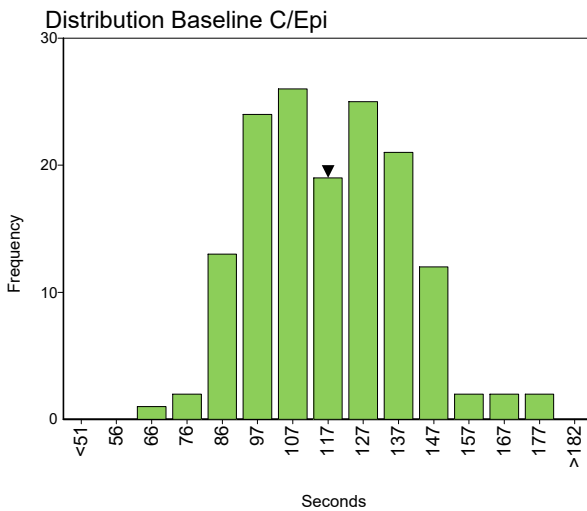
Appendices are an integral part of the total report.

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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	129	253	150 - 423	295		
Mean Platelet Volume	fL	110	9.8	7.1 - 12.6	9.1		
Haematocrit	L/L	123	0.41	0.31 - 0.69	0.40		
VWF:AG	%	55	116	66 - 214			
VWF:RCo	%	26	110	75 - 200			
VWF:Activity	%	34	109	64 - 197			
VWF:CBA	%	11	114	79 - 274			
FVIII:C	%	49	138	59 - 304			
Baseline C/Epi	seconds	149	117	69 - 174	118		
Baseline C/ADP	seconds	149	89	57 - 128	101		



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	130	0	0	1	Normal		
Mean Platelet Volume	105	5	1	2	Normal		
Haematocrit	122	1	2	0	Normal		
VWF:AG	53	1	1	1			
VWF:RCo	26	0	0	1			
VWF:Activity	33	0	1	1			
VWF:CBA	10	0	1	1			
FVIII:C	44	1	3	2			
Baseline C/Epi	145	3	0	1	Normal		
Baseline C/ADP	143	7	0	0	Normal		

Comments:

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

- 192 - (Mean Platelet Volume) : 90.7 fL
- 226 - (Mean Platelet Volume) : 0.42 fL
- 1247 - (Haematocrit) : 361 L/L
- 1352 - (Platelet Count) : 216.000 x 10⁹/L
- 1352 - (Mean Platelet Volume) : 90.0 fL
- 1474 - (VWF:AG / VWF:RCo / VWF: Activity : 0%
- VWF:CBA / FVIII:C)

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	23.132		
Sample Details	Normal PFA sample		
Prior Use	None		
Unit	seconds		
Expiry Date	16-februari-2025		
Homogeneity	-	Homogeneity Parameter	n.a.
Number of Participants	174		
Number of Responders	161	Response Rate	93 %
Comments	Three participants reported error codes for the measurement with the C/Epi cartridge and one participant reported an error code for the measurement with the C/ADP cartridge. Furthermore, eleven participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi and/or C/ADP cartridge.		

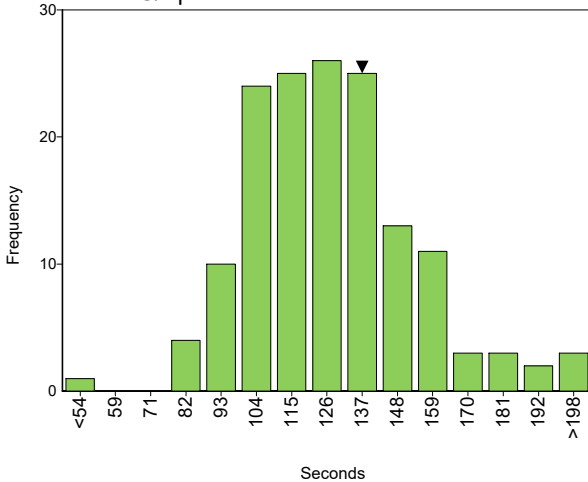
Classification for sample 23.132:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	125	10	15	5	Normal		
C/ADP	114	15	21	2	Normal		

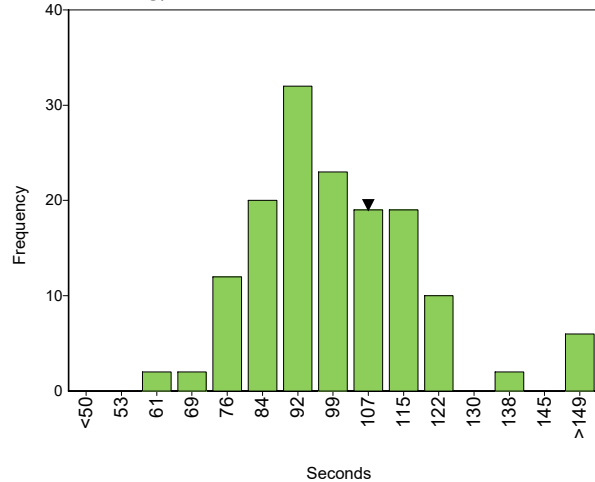
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	150	126	2.4	19.1	47 - 233	141	0.63				
C/ADP	147	99	1.7	16.7	58 - 272	108	0.53				

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	116
Borderline	15
Mild Defect	7
Severe Defect	4
Aspirin-like Defect	6
Unable to Interpret	3
Test Failure	7
Other	2
No Conclusion	3

Normal		
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Conclusion Comments:

About 71% of the participants correctly classified this sample as normal. Surprisingly, about 10% of the participants observed a defect in this sample and also about 9% 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 23.133
Sample Details PFA sample with a severe defect
Prior Use None
Unit seconds
Expiry Date 16-februari-2025
Homogeneity 0.0 % **Homogeneity Parameter** C/Epi
Number of Participants 174
Number of Responders 161 **Response Rate** 93 %
Comments The following participant reported a deviating result which was excluded in the statistical evaluation:
251 - (C/ADP) : 0 sec

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.

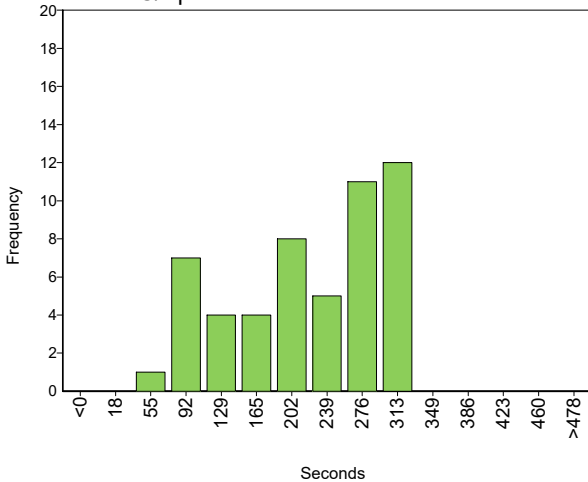
Classification for sample 23.133:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
					Abnormal		
C/Epi	12	3	134	6	Abnormal		
C/ADP	7	0	136	16	Abnormal		

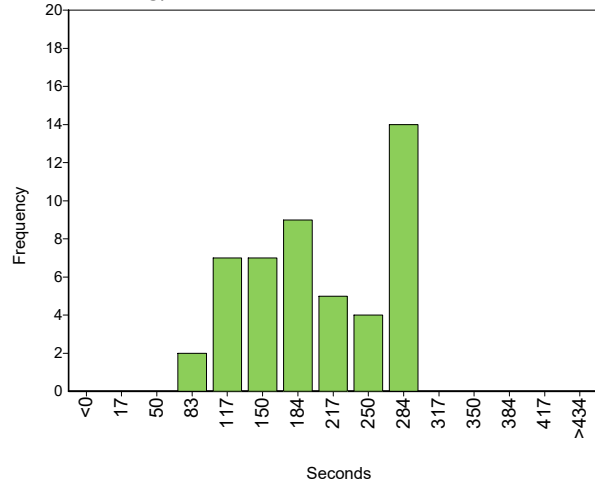
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
						>300					
C/Epi	52	217	15.1	40.0	73 - 301	>300					
C/ADP	48	206	13.7	36.7	82 - 300	>300					

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	3
Borderline	0
Mild Defect	7
Severe Defect	111
Aspirin-like Defect	7
Unable to Interpret	8
Test Failure	14
Other	2
No Conclusion	10

Severe Defect		
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Conclusion Comments:

About 69% of the participants correctly classified this as sample with a severe defect. There were also a number of participants that observed a test failure or were not able to interpret the results or did not give a conclusion. Surprisingly, three participants classified this sample as normal.

