ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2025-P3
PFA 100/200
Labcode 1492

Date of Issue : 03-November-2025

Survey : 2025-P3

Report : PFA 100/200

Note:
In the Survey Manual 2025 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.
This Survey Manual 2025 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

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.

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.

Complaints
Any complaints regarding this survey report should be reported to the ECAT before **December 16th, 2025.**
Complaints received after this date will not be taken into consideration.

This report is authorized by:

Dr. P. Meijer
Director

Note: The current Survey Manual can be downloaded from the 'Participant Area' of the ECAT website. Login and select the option 'View Documents'.

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

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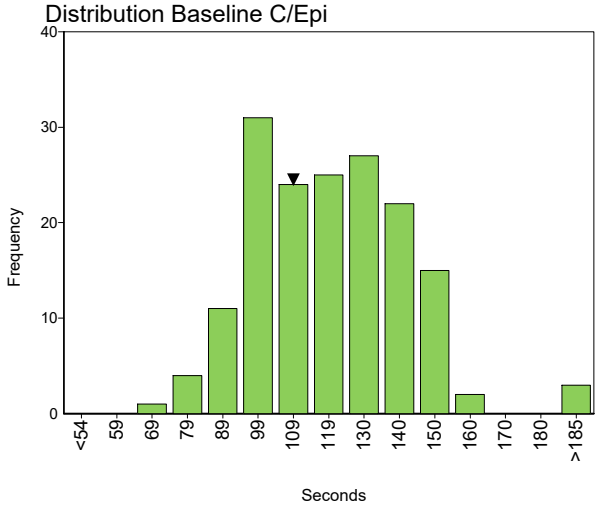
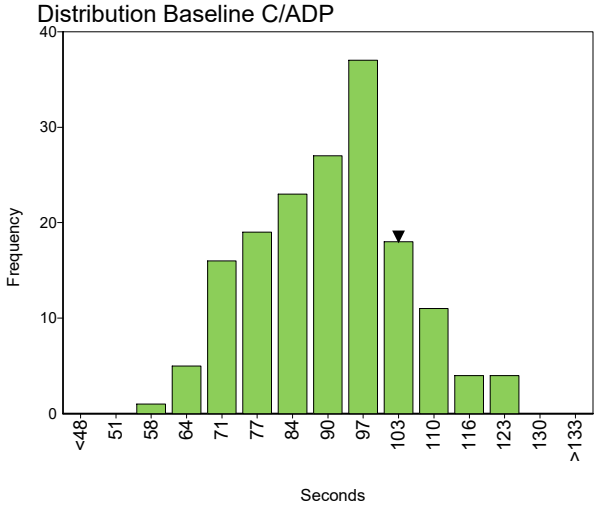
Baseline results from donor native blood:

Test Parameter	Unit	n	Mean	Range	Own Result	Own Result	Own Result
Platelet Count	x10⁹/L	151	247	121 - 436	262		
Mean Platelet Volume	fL	130	9.9	6.1 - 12.5	8.8		
Haematocrit	L/L	148	0.41	0.33 - 0.50	0.40		
VWF:AG	%	69	112	64 - 230			
VWF:RCo	%	29	100	44 - 171			
VWF:Activity	%	47	109	66 - 190			
VWF:CBA	%	24	116	49 - 182			
FVIII:C	%	67	128	53 - 289			
Baseline C/Epi	seconds	165	119	65 - 194	110		
Baseline C/ADP	seconds	165	90	55 - 122	105		

Distribution Baseline C/Epi



Distribution Baseline C/ADP



Classification baseline results from donor native blood:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
Platelet Count	147	4	1	0	Normal		
Mean Platelet Volume	126	3	4	0	Normal		
Haematocrit	145	2	0	1	Normal		
VWF:AG	64	0	5	3			
VWF:RCo	26	3	0	3			
VWF:Activity	45	0	2	6			
VWF:CBA	24	0	0	3			
FVIII:C	58	5	4	4			
Baseline C/Epi	158	4	2	1	Normal		
Baseline C/ADP	160	5	0	0	Normal		

Comments:

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

277 - (FVIII:C) : 1.33 %
365 - (Mean Platelet Volume) : 89.0 fL
1322 - (Mean Platelet Volume) : 40.9 fL
1432 - (VWF:activity) : 0 % (3 instruments)
1552 - (Mean Platelet Volume) : 88.4 fL
1552 - (Mean Platelet Volume) : 88.4 fL
4567 - (Platelet Count) : 2.73 x 10^9/L

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.

PFA 100/200

PFA 100/200

Sample No	25.200
Sample Details	PFA sample with a severe defect
Prior Use	None
Unit	seconds
Expiry Date	18-July-2025
Homogeneity	0.0 %
Homogeneity Parameter	n.a.
Number of Participants	184
Number of Responders	177
Response Rate	96 %
Comments	For the C/Epi cartridge147 participants reported a result above the upper limit of the measuring range [> (value)]. For the C/ADP cartridge 148 participants reported a result above the upper limit of the measuring range [> (value)]. Two participants reported an error code for the measurement with the C/Epi cartridge and also two participant reported an error code for the measurement with the C/ADP cartridge. No mean, standard deviation and coefficient of variation could be calculated with Algorithm A due to the distribution width of the results for the C/Epi cartridge.

Classification for sample 25.200:

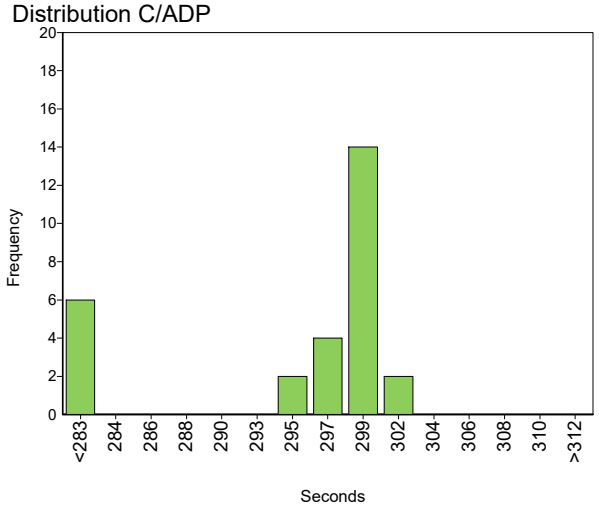
Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	1	0	169	3	Abnormal		
C/ADP	1	1	170	3	Abnormal		

Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	29	300			264 - 301	>300					
C/ADP	28	297	1.1	1.6	152 - 301	>300					

No data for graph

Distribution C/ADP



Final Conclusion:

	N
Normal	3
Borderline	0
Mild Defect	1
Severe Defect	154
Aspirin-like Defect	0
Unable to Interpret	4
Test Failure	6
Other	3
No Conclusion	13

Severe Defect		

Conclusion Comments:

Almost all participants (approx. 97%) correctly classified this as a sample with a severe defect. There were also some participants that observed a test failure or were not able to interpret the results or did not give a conclusion.

PFA 100/200

PFA 100/200

Sample No	25.201
Sample Details	PFA sample with a aspirin-like defect
Prior Use	None
Unit	seconds
Expiry Date	18-July-2025
Homogeneity	0.0 %
Homogeneity Parameter	n.a.
Number of Participants	184
Number of Responders	177
Response Rate	96 %
Comments	For the C/Epi cartridge141 participants reported a result above the upper limit of the measuring range [> (value)]. For the C/ADP cartridge 33 participants reported a result above the upper limit of the measuring range [> (value)]. One participant reported an error code for the measurement with the C/Epi cartridge and also one participant reported an error code for the measurement with the C/ADP cartridge.

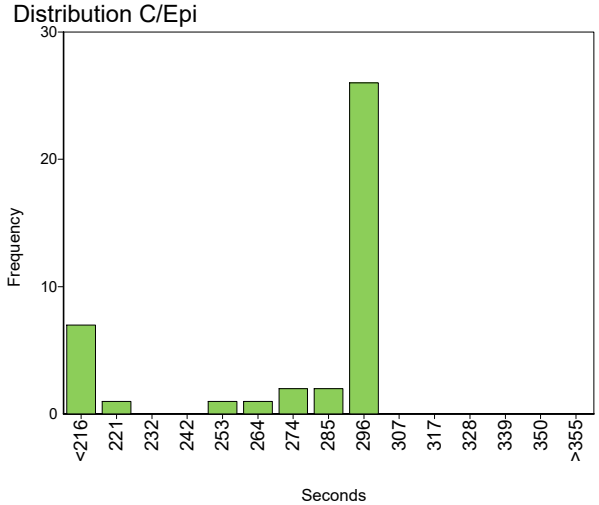
Classification for sample 25.201:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	6	0	169	1	Abnormal		
C/ADP	37	17	127	2	Abnormal		

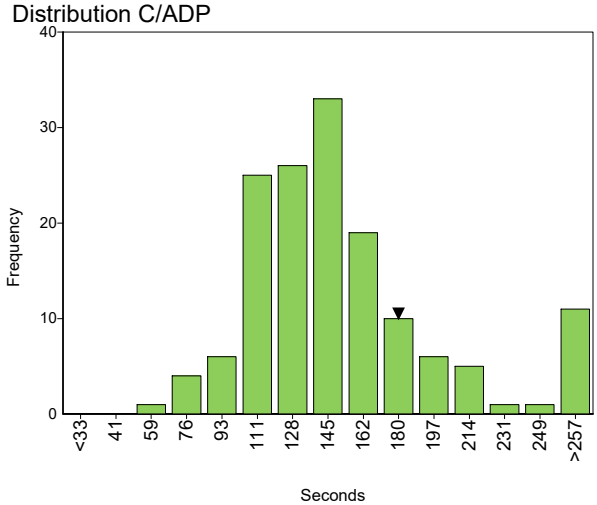
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	40	285	4.6	8.1	101 - 301	>300					
C/ADP	148	145	3.8	25.8	61 - 300	173	0.75				

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	6
Borderline	1
Mild Defect	15
Severe Defect	79
Aspirin-like Defect	57
Unable to Interpret	6
Test Failure	2
Other	5
No Conclusion	14

Severe Defect		

Conclusion Comments:

About 36% of the participants correctly classified this as a sample with an aspirin-like defect. Fifty percent of the participants classified this as a sample with a severe defect. This is most likely because they found a prolonged closure time for both the C/Epi and C/ADP cartridges. About 9% of the participants classified this as a sample with a mild defect. There were also some participants that observed a test failure or were not able to interpret the results or did not give a conclusion.