

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2025-P1**

**PFA 100/200**

**Labcode 1492**

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Date of Issue : 29-April-2025

Survey : 2025-P1

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 **June 24th, 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'.

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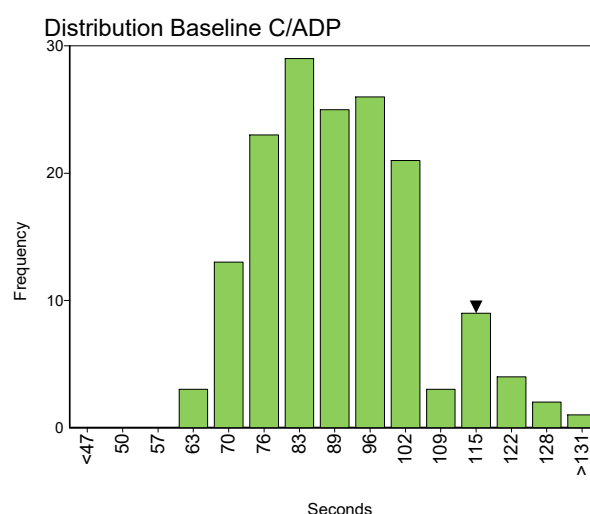
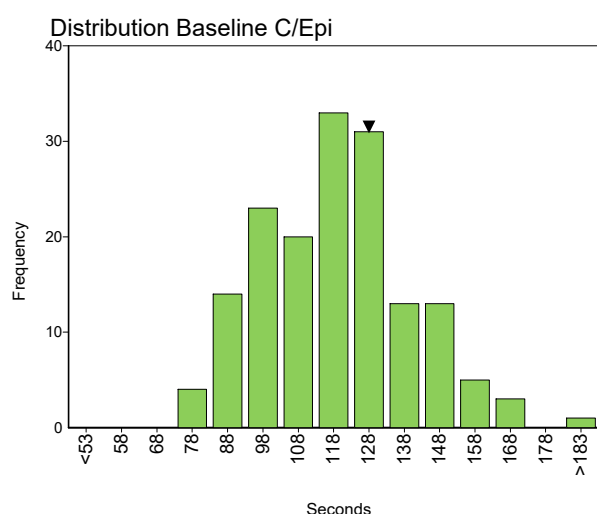
Director: Dr. P. Meijer  
ECAT Office  
P.O. Box 107  
2250 AC Voorschoten, The Netherlands  
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919  
E-mail: [info@ecat.nl](mailto:info@ecat.nl)  
Website: [www.ecat.nl](http://www.ecat.nl)  
VAT number: NL802836872B01

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Appendices are an integral part of the total report.

**PFA 100/200**
**PFA 100/200**
**Baseline results from donor native blood:**

Test Parameter	Unit	n	Mean	Range	Own Result	Own Result	Own Result
Platelet Count	x10 <sup>9</sup> /L	147	256	141 - 635	242		
Mean Platelet Volume	fL	126	9.9	7.0 - 12.7	9.7		
Haematocrit	L/L	141	0.41	0.34 - 0.49	0.45		
VWF:AG	%	64	112	54 - 196			
VWF:RCo	%	26	96	40 - 146			
VWF:Activity	%	44	122	59 - 229			
VWF:CBA	%	14	117	46 - 179			
FVIII:C	%	61	127	57 - 228			
Baseline C/Epi	seconds	160	118	75 - 187	125		
Baseline C/ADP	seconds	159	89	60 - 135	118		


**Classification baseline results from donor native blood:**

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
Platelet Count	143	3	1	0	Normal		
Mean Platelet Volume	119	5	3	1	Normal		
Haematocrit	134	5	2	0	Normal		
VWF:AG	58	2	5	1			
VWF:RCo	24	2	0	2			
VWF:Activity	42	0	2	2			
VWF:CBA	14	1	0	2			
FVIII:C	54	2	5	1			
Baseline C/Epi	157	0	2	0	Normal		
Baseline C/ADP	152	4	2	0	Normal		

**Comments:**

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

1346 - (Mean Platelet Volume) : 82.0 fL

1593 - (Mean Platelet Volume) : 88.4 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.

**PFA 100/200**
**PFA 100/200**

Sample No	25.81		
Sample Details	Normal PFA sample		
Prior Use	None		
Unit	seconds		
Expiry Date	01-October-2026		
Homogeneity	0.0 %	Homogeneity Parameter	n.a.
Number of Participants	184		
Number of Responders	173	Response Rate	94 %
Comments	The following participant reported a deviating result which was excluded from the statistical evaluation: <b>1542 - (C/ADP) : 0 sec.</b>		

One participant reported a result above the upper limit of the measuring range [ > (value)] with the C/Epi cartridge. For the C/ADP cartridge 6 participants reported a result above the upper limit of the measuring range [ > (value)].

Four participants reported an error code for the measurement with the C/Epi cartridge and 1 participant reported an error code for the measurement with the C/ADP cartridge.

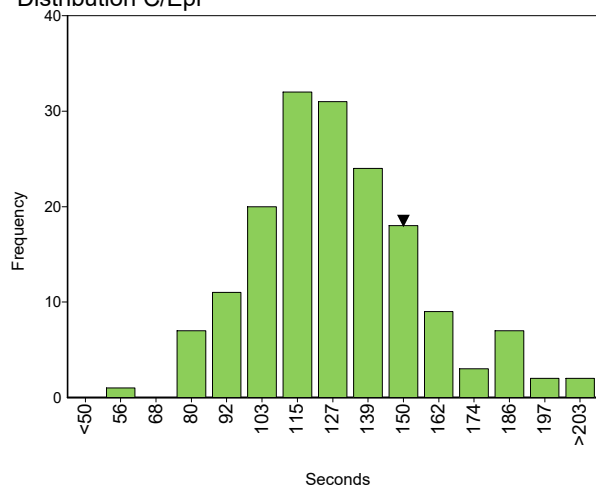
**Classification for sample 25.81:**

Test Parameter	Normal	Borderline	Abnormal	No Classification			
					Own Result	Own Result	Own Result
C/Epi	139	10	14	4	Normal		
C/ADP	125	17	24	2	Normal		

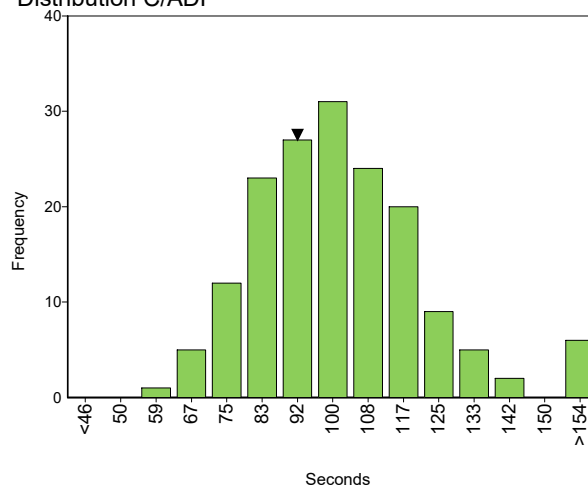
**Sample results:**

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	167	127	2.5	20.1	58 - 282	151	0.95				
C/ADP	165	100	1.8	18.0	59 - 189	95	-0.29				

Distribution C/Epi



Distribution C/ADP


**Final Conclusion:**

	N
Normal	127
Borderline	13
Mild Defect	13
Severe Defect	2
Aspirin-like Defect	9
Unable to Interpret	2
Test Failure	7
Other	0
No Conclusion	4

Normal		

**Conclusion Comments:**

About 72% of the participants correctly classified this sample as normal.

Surprisingly, about 14% of the participants observed a defect in this sample and also about 7% of the participants 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.

PFA 100/200

PFA 100/200

Sample No 25.82  
Sample Details PFA sample with a severe defect  
Prior Use None  
Unit seconds  
Expiry Date 01-October-2026  
Homogeneity 0.0 % Homogeneity Parameter n.a.  
Number of Participants 184  
Number of Responders 173 Response Rate 94 %  
Comments For the C/Epi cartridge 134 participants reported a result above the upper limit of the measuring range [ $>$  (value)]. For the C/ADP cartridge 141 participants reported a result above the upper limit of the measuring range [ $>$  (value)].

Five participants reported an error code for the measurement with the C/Epi cartridge and three participants reported an error code for the measurement with the C/ADP cartridge.

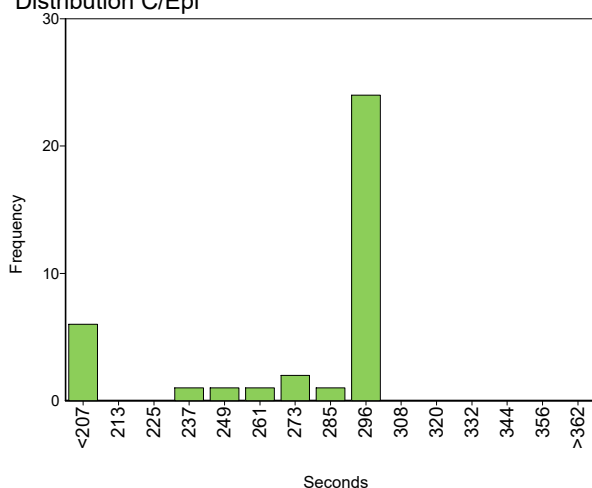
Classification for sample 25.82:

Test Parameter	Normal	Borderline	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	5	2	160	3	Abnormal		
C/ADP	1	0	172	1	Abnormal		

Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	36	285	5.4	9.0	94 - 300	>300					
C/ADP	30	300			166 - 300	>300					

Distribution C/Epi



No data for graph

Final Conclusion:

	N
Normal	0
Borderline	0
Mild Defect	0
Severe Defect	162
Aspirin-like Defect	2
Unable to Interpret	1
Test Failure	5
Other	1
No Conclusion	6

Severe Defect		

Conclusion Comments:

Almost all participants (approx. 92%) correctly classified this as 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.