

# ECAT FOUNDATION

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## REPORT



**SURVEY 2024-P3**

**PFA 100/200**

**Labcode 1492**

Copyright © 2024  
ECAT Foundation

Date of Issue : 31-oktober-2024

Survey : 2024-P3

Report : PFA 100/200

**Note:**

In the Survey Manual 2024 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2024 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 **December 12th, 2024**.

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  
General terms of delivery are applicable to all our services.

All rights reserved. No part of this report may be reproduced, stored in a retrieval system, or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior permission from the ECAT Foundation.

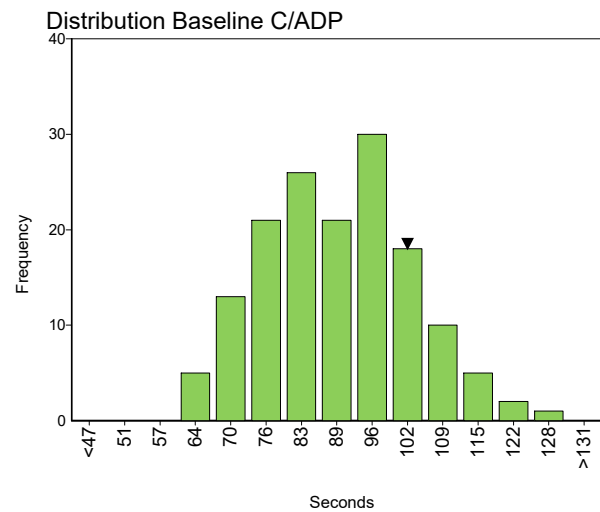
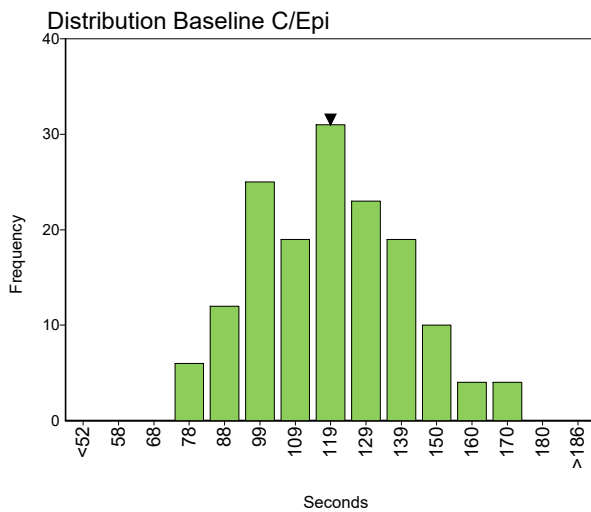
Appendices are an integral part of the total report.

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	134	251	90 - 368	299		
Mean Platelet Volume	fL	117	9.9	6.7 - 13.3	8.7		
Haematocrit	L/L	130	0.41	0.33 - 0.52	0.42		
VWF:AG	%	62	116	68 - 219			
VWF:RCo	%	27	106	58 - 144			
VWF:Activity	%	39	114	67 - 208			
VWF:CBA	%	15	107	59 - 189			
FVIII:C	%	59	133	80 - 229			
Baseline C/Epi	seconds	153	119	76 - 175	115		
Baseline C/ADP	seconds	152	89	62 - 130	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	135	1	1	1	Normal		
Mean Platelet Volume	116	3	0	0	Normal		
Haematocrit	127	4	1	0	Normal		
VWF:AG	59	1	2	3			
VWF:RCo	27	0	0	3			
VWF:Activity	39	0	1	4			
VWF:CBA	16	0	0	4			
FVIII:C	54	1	4	3			
Baseline C/Epi	150	4	0	0	Normal		
Baseline C/ADP	147	6	0	0	Normal		

Comments:

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

- 1426 - (Mean Platelet Volume) : 91.4fL
- 4567 - (Platelet Count) : 2.41 \*10<sup>9</sup>/L
- 4567 - (Haematocrit) : 3.95 L/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** 24.194  
**Sample Details** PFA sample with a mild defect  
**Prior Use**  
**Unit** seconds  
**Expiry Date** 11-juli-2024  
**Homogeneity** - **Homogeneity Parameter** C/Epi  
**Number of Participants** 184  
**Number of Responders** 167 **Response Rate** 91 %  
**Comments** The following participant reported deviating results which were excluded in the statistical evaluation:

**973** - (C/Epi and C/ADP) : 0 sec.

Two participants reported an error code for the measurement with the C/Epi cartridge and also two participants reported an error code for the measurement with the C/ADP cartridge. Furthermore, 4 participants reported a result above the upper limit of the measuring range [ > (value)] for the C/Epi cartridge. For the C/ADP cartridge one participant reported a result above the upper limit of the measuring range [ > (value)], while also one participant reported a value < 200 sec.

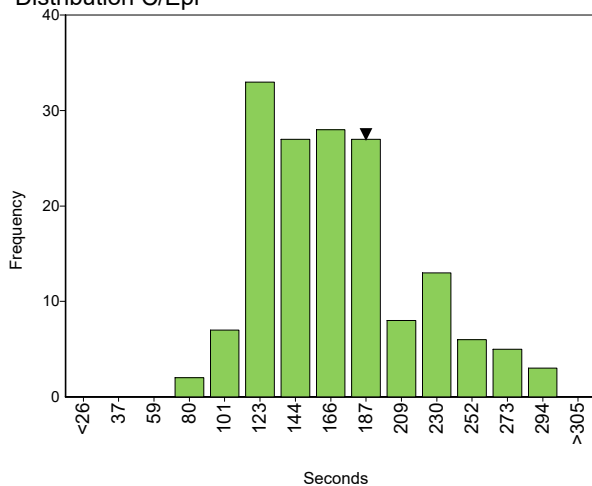
**Classification for sample 24.194:**

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	71	9	81	3	Abnormal		
C/ADP	63	11	85	5	Abnormal		

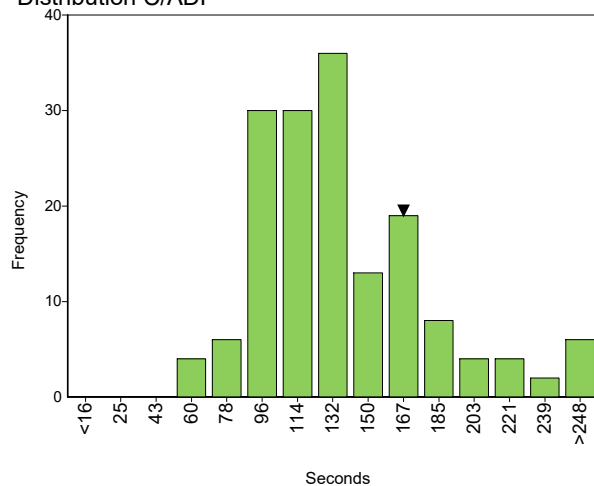
**Sample results:**

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	160	166	4.6	28.0	82 - 300	196	0.65				
C/ADP	162	132	3.8	29.3	56 - 300	164	0.84				

Distribution C/Epi



Distribution C/ADP



**Final Conclusion:**

	N
Normal	45
Borderline	15
Mild Defect	50
Severe Defect	22
Aspirin-like Defect	14
Unable to Interpret	2
Test Failure	6
Other	4
No Conclusion	11

Mild Defect		

**Conclusion Comments:**

About 51% (n=86) of the participants classified this as sample with a defect.

Fifty-eight percent (n=50) of them correctly indicated a mild 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.

About 27% (n=45) of the participants classified this sample with a mild defect as a normal sample!

**PFA 100/200**

**PFA 100/200**

**Sample No** 24.195  
**Sample Details** Normal PFA sample  
**Prior Use**  
**Unit** seconds  
**Expiry Date** 11-juli-2024  
**Homogeneity** - **Homogeneity Parameter** C/Epi  
**Number of Participants** 184  
**Number of Responders** 167 **Response Rate** 91 %  
**Comments** The following participant reported a deviating result which was excluded in the statistical evaluation:  
**973 - (C/ADP) : 0 sec.**

Five participants reported an error code for the measurement with the C/Epi cartridge. Furthermore, 1 participant reported a result above the upper limit of the measuring range [ > (value)] for the C/Epi cartridge. For the C/ADP cartridge one participant reported a value < 200 sec.

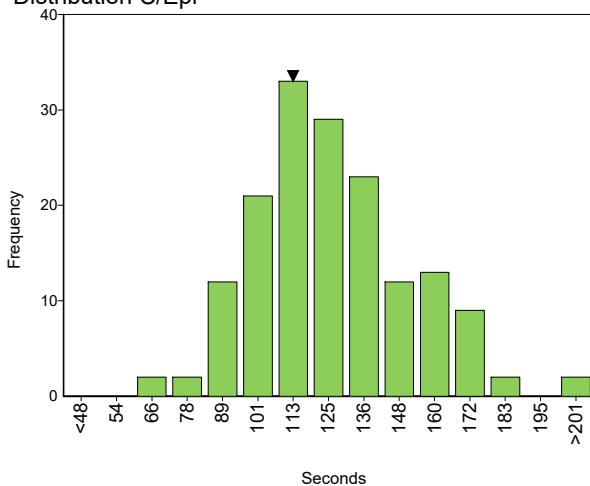
**Classification for sample 24.195:**

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	132	7	19	6	Normal		
C/ADP	122	17	25	3	Normal		

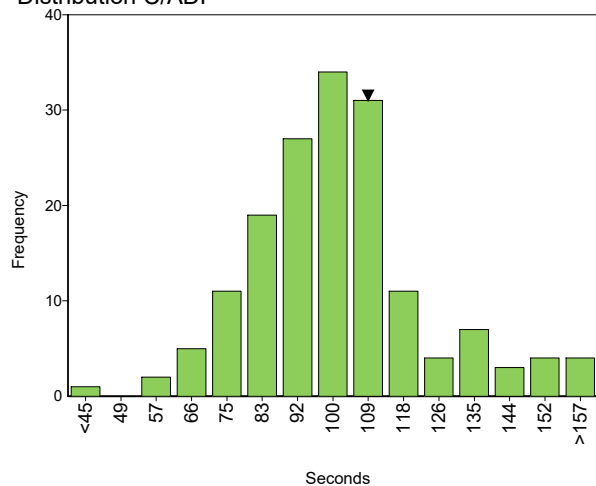
**Sample results:**

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	161	125	2.5	20.5	67 - 248	108	-0.65				
C/ADP	164	100	1.8	18.6	40 - 190	113	0.67				

Distribution C/Epi



Distribution C/ADP



**Final Conclusion:**

	N
Normal	112
Borderline	18
Mild Defect	15
Severe Defect	1
Aspirin-like Defect	4
Unable to Interpret	5
Test Failure	5
Other	1
No Conclusion	7

Normal		

**Conclusion Comments:**

About 67% of the participants correctly classified this sample as normal.

Surprisingly, about 12% of the participants observed a defect in this sample and also about 11% 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.