

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2026-P1

PFA 100/200

Labcode 1492

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Date of Issue : 01-May-2026

Survey : 2026-P1

Report : PFA 100/200

Note:

In the Survey Manual 2026 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2026 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 23rd, 2026**.

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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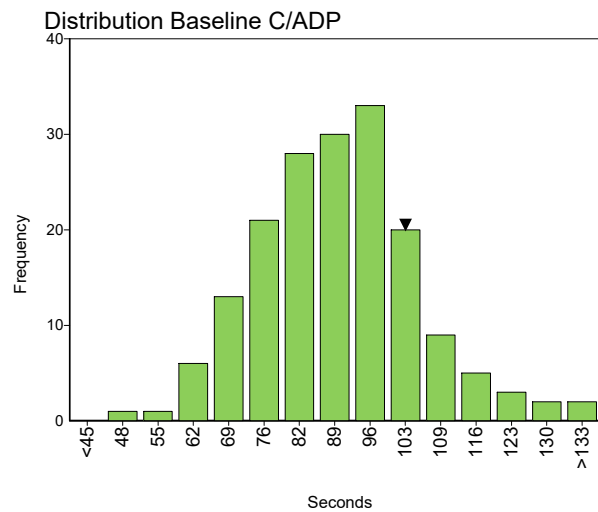
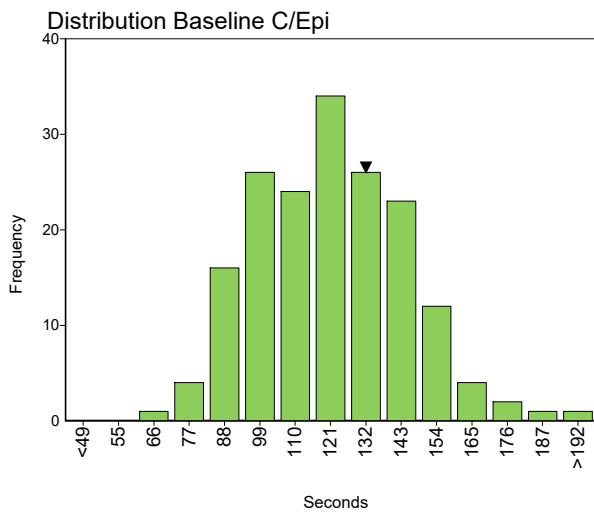
Appendices are an integral part of the total report.

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 ⁹ /L	157	254	167 - 438	255		
Mean Platelet Volume	fL	133	9.9	7.1 - 20.0	9.8		
Haematocrit	L/L	153	0.41	0.31 - 0.51	0.49		
VWF:AG	%	71	112	57 - 213			
VWF:RCo	%	30	90	42 - 152			
VWF:Activity	%	50	112	36 - 179			
VWF:CBA	%	19	114	75 - 174			
FVIII:C	%	64	129	54 - 204			
Baseline C/Epi	seconds	174	121	70 - 223	134		
Baseline C/ADP	seconds	174	89	50 - 180	103		



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	159	0	0	0	Normal		
Mean Platelet Volume	133	3	2	2	Normal		
Haematocrit	146	7	2	0	Normal		
VWF:AG	67	1	3	0			
VWF:RCo	24	3	3	0			
VWF:Activity	49	0	1	0			
VWF:CBA	19	0	0	0			
FVIII:C	62	1	3	0			
Baseline C/Epi	164	5	3	1	Normal		
Baseline C/ADP	166	2	4	3	Normal		

Comments:

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

104 - (Platelet Count)	: 323000 x 10 ⁹ /L
116 - (Haematocrit)	: 3.9 L/L
192 - (Mean Platelet Volume)	: 93.4 fL
203 - (Mean Platelet Volume)	: 94.1 fL
203 - (Haematocrit)	: 13.6 L/L
277 - (FVIII:C)	: 1.05 %
550 - (Mean Platelet Volume)	: 88.4 fL
670 - (Mean Platelet Volume)	: 85.9 fL
747 - (Mean Platelet Volume)	: 38.0 fL
1274 - (Mean Platelet Volume)	: 83.9 fL
1540 - (Mean Platelet Volume)	: 89.0fL
1747 - (Platelet Count)	: 267000 x 10 ⁹ /L
4567 - (Platelet Count)	: 2.27 x 10 ⁹ /L
4567 - (Haematocrit)	: 3.94 L/L

The baseline test results reported by all participants indicate that, in almost all cases, a normal donor was used.

PFA 100/200

PFA 100/200

Sample No 26.85
Sample Details Sample with an aspirin-like defect
Prior Use None
Unit seconds
Expiry Date 19-October-2027
Homogeneity 10.8 % **Homogeneity Parameter** EPI
 For any method used for the measurement of this parameter with a **CV ≤ 36.0%** 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 203
Number of Responders 189 **Response Rate** 93 %

Comments For the C/Epi cartridge 150 participants reported a result above the upper limit of the measuring range [$>$ (value)]. For the C/ADP cartridge 40 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 two participants reported an error code for the measurement with the C/ADP cartridge.

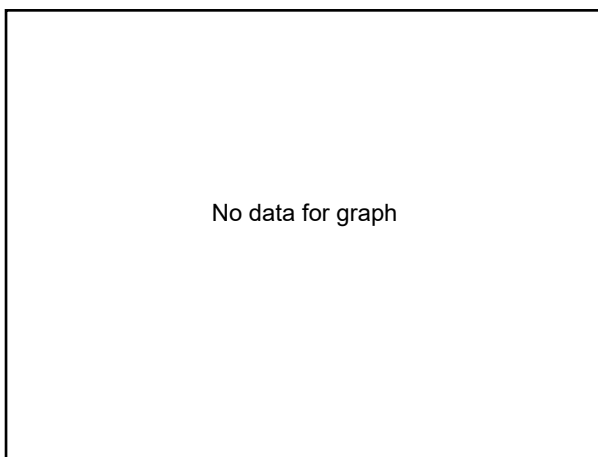
No mean, standard deviation and coefficient of variation could be calculated with Algorithm A due to the distribution width of the results for the C/Epi cartridge.

Classification for sample 26.85:

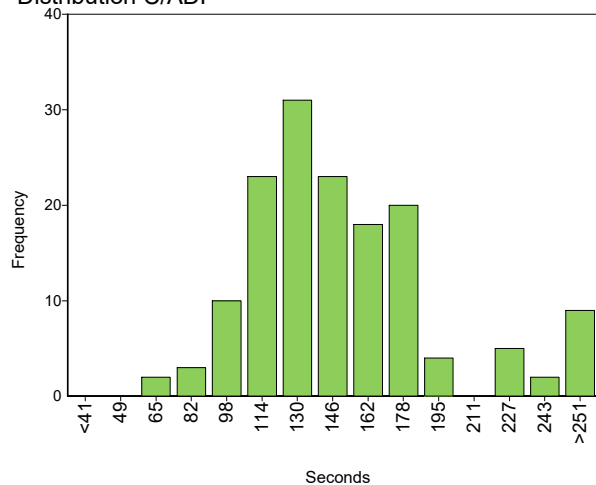
Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
					Abnormal		
C/Epi	1	0	182	2	Abnormal		
C/ADP	31	16	139	1	Abnormal		

Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	39	300			72 - 301	>300					
C/ADP	150	146	3.6	23.9	66 - 301	>300					



Distribution C/ADP



Final Conclusion:

	N
Normal	1
Borderline	0
Mild Defect	24
Severe Defect	82
Aspirin-like Defect	63
Unable to Interpret	4
Test Failure	2
Other	5
No Conclusion	14

Severe Defect		

Conclusion Comments:

About 32% of the participants correctly classified this as a sample with an aspirin-like defect. Forty-two percent of the participants classified this as a sample with a severe defect. This is most likely because a prolonged closure time for both the C/Epi and C/ADP cartridges was found. About 12% 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.

An aspirin-like defect normally results in a prolonged collagen/epinephrine (C/Epi) closure time and a normal collagen/ADP (C/ADP) closure time.

In this sample a large number of participants also found an abnormal collagen/ADP (C/ADP) closure time. This is most likely an artefact of the sample.

PFA 100/200

PFA 100/200

Sample No 26.86
Sample Details Sample with a severe defect
Prior Use None
Unit seconds
Expiry Date 29-October-2027
Homogeneity 4.2 % **Homogeneity Parameter** EPI
 For any method used for the measurement of this parameter with a **CV ≤ 14.0%** 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 203
Number of Responders 189 **Response Rate** 93 %

Comments For both the C/Epi cartridge (n=158) and for the C/ADP cartridge (n=157) a large proportion of the 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 two participants reported an error code for the measurement with the C/ADP cartridge.

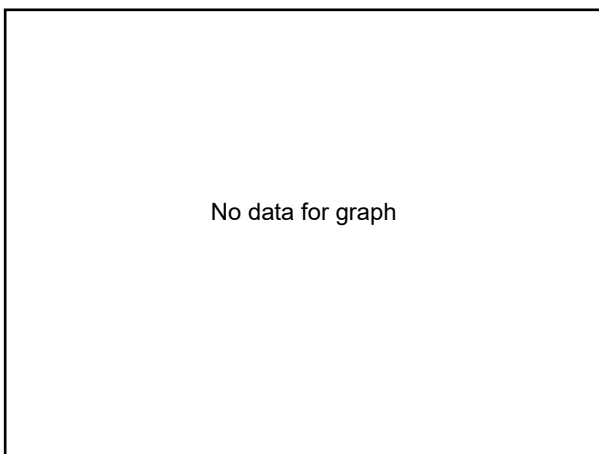
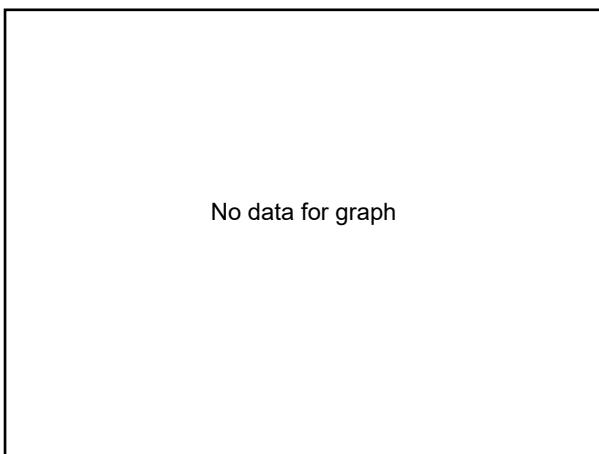
No mean, standard deviation and coefficient of variation could be calculated with Algorithm A due to the distribution width of the remaining results for both the C/Epi and C/ADP cartridges.

Classification for sample 26.86:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	0	0	184	2	Abnormal		
C/ADP	1	0	189	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	30	300			191 - 300	>300					
C/ADP	33	300			206 - 301	>300					



Final Conclusion:

	N
Normal	0
Borderline	0
Mild Defect	0
Severe Defect	166
Aspirin-like Defect	4
Unable to Interpret	4
Test Failure	4
Other	6
No Conclusion	11

Severe Defect		

Conclusion Comments:

The vast majority of participants (approx. 85%) 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.