ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2024-P1
PFA 100/200
Labcode 1492

Date of Issue : 07-May-2024

Survey : 2024-P1

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 **June 21st, 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

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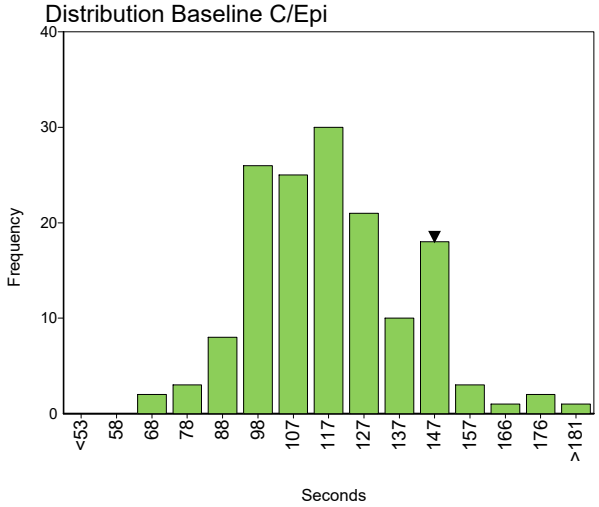
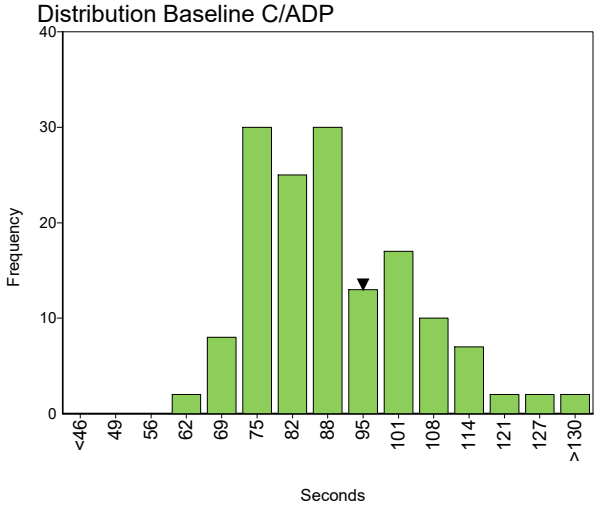
Baseline results from donor native blood:

Test Parameter	Unit	n	Mean	Range	Own Result	Own Result	Own Result
Platelet Count	x10⁹/L	137	257	161 - 408	288		
Mean Platelet Volume	fL	118	9.7	6.6 - 12.6	8.7		
Haematocrit	L/L	130	0.41	0.32 - 0.51	0.40		
VWF:AG	%	71	120	76 - 213			
VWF:RCo	%	28	109	73 - 161			
VWF:Activity	%	44	122	62 - 191			
VWF:CBA	%	16	113	74 - 166			
FVIII:C	%	64	139	71 - 229			
Baseline C/Epi	seconds	150	117	67 - 184	150		
Baseline C/ADP	seconds	148	88	63 - 147	96		

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	137	0	0	0	Normal		
Mean Platelet Volume	119	4	0	0	Normal		
Haematocrit	123	7	2	0	Normal		
VWF:AG	68	1	2	0			
VWF:RCo	27	1	0	2			
VWF:Activity	43	1	0	0			
VWF:CBA	17	0	0	0			
FVIII:C	55	3	5	1			
Baseline C/Epi	144	5	1	0	Normal		
Baseline C/ADP	140	8	0	0	Normal		

Comments:

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

550 - (Mean Platelet Volume)	: 91.3 fL
1018 - (Mean Platelet Volume)	: 88.7 fL
1043 - (Mean Platelet Volume)	: 88.7 fL
1045 - (Mean Platelet Volume)	: 85.7 fL
1356 - (Mean Platelet Volume)	: 82.6 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.

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Sample No 24.79
Sample Details PFA sample with a severe defect
Prior Use None
Unit seconds
Expiry Date 29-January-2026
Homogeneity 5.6 % **Homogeneity Parameter** C/Epi
For any method used for the measurement of this parameter with a **CV ≤ 18.7%** 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 174
Number of Responders 164 **Response Rate** 94 %
Comments The following participant reported a deviating result which was excluded in the statistical evaluation:
1472 - (C/ADP) : 0 sec.

Four participants reported an error code for the measurement with the C/Epi cartridge and also four participants reported an error code for the measurement with the C/ADP cartridge. Furthermore, 93 participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi cartridge. For the C/ADP cartridge 77 participants reported a result above the upper limit of the measuring range [> (value)].

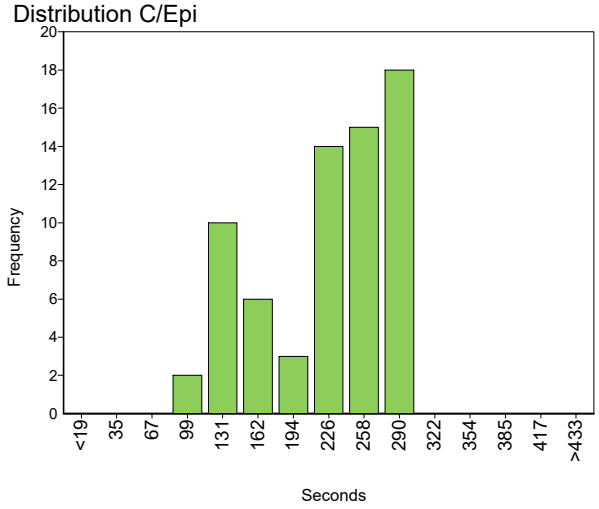
Classification for sample 24.79:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	10	3	145	4	Abnormal		
C/ADP	6	2	145	5	Abnormal		

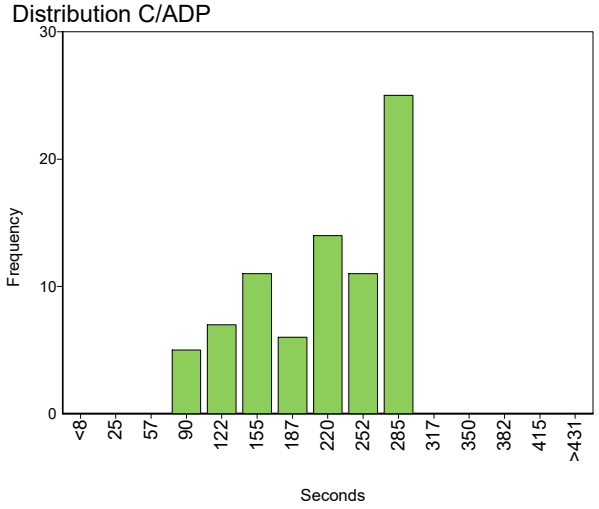
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	68	226	10.5	30.5	96 - 301	>300					
C/ADP	79	220	9.9	32.1	77 - 300	>300					

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	8
Borderline	0
Mild Defect	7
Severe Defect	115
Aspirin-like Defect	11
Unable to Interpret	5
Test Failure	8
Other	5
No Conclusion	8

Severe Defect		

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, eight participants classified this sample as normal.

PFA 100/200	PFA 100/200

Sample No 24.80
Sample Details PFA sample with a mild defect
Prior Use None
Unit seconds
Expiry Date 29-January-2026
Homogeneity 21.7 % **Homogeneity Parameter** C/Epi
For any method used for the measurement of this parameter with a **CV ≤ 72.3%** 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 174
Number of Responders 164 **Response Rate** 94 %
Comments The following participant reported a deviating result which was excluded in the statistical evaluation:
296A - (C/Epi) : 0 sec.

Three participants reported an error code for the measurement with the C/Epi cartridge and one participant reported an error code for the measurement with the C/ADP cartridge.
Furthermore, 6 participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi cartridge.For the C/ADP cartridge 3 participants reported a result above the upper limit of the measuring range [> (value)].

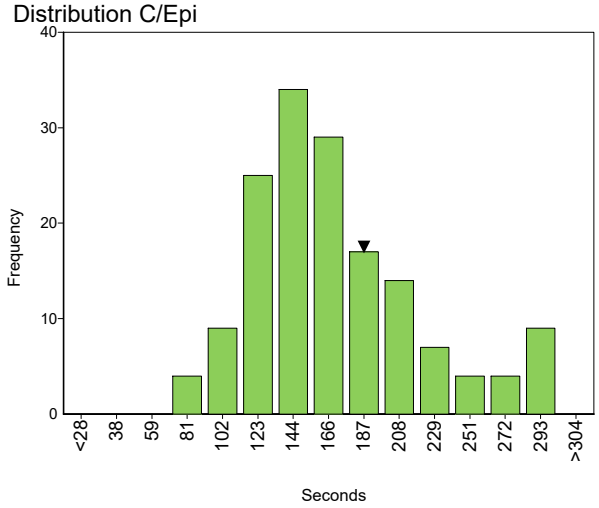
Classification for sample 24.80:

Test Parameter	Normal	Borderine	Abnormal	No Classification	Own Result	Own Result	Own Result
C/Epi	69	7	82	4	Abnormal		
C/ADP	65	18	77	1	Abnormal		

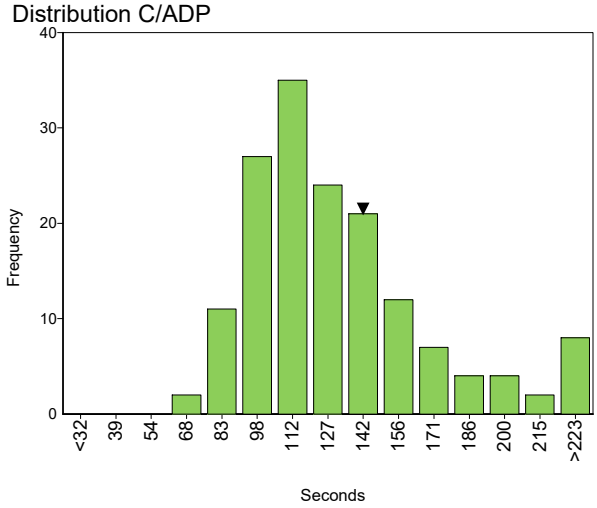
Sample results:

Parameter	n	assigned value	Uncert.	CV (%)	range	your result	z-score	your result	z-score	your result	z-score
C/Epi	156	166	4.6	27.8	82 - 300	194	0.62				
C/ADP	157	127	3.2	25.0	70 - 300	148	0.66				

Distribution C/Epi



Distribution C/ADP



Final Conclusion:

	N
Normal	58
Borderline	9
Mild Defect	39
Severe Defect	25
Aspirin-like Defect	18
Unable to Interpret	6
Test Failure	5
Other	3
No Conclusion	5

Mild Defect		

Conclusion Comments:

Only 49% (n=82) of the participants classified this as sample with a defect.
About 48% (n=39) 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 35% (n=58) of the participants classified this sample with a mild defect as a normal sample!