# ECAT FOUNDATION

## External quality Control for Assays and Tests

### With a focus on Thrombosis and Haemostasis

# REPORT

# SURVEY 2023-P4
# PFA 100/200
# Labcode 1492

Date of Issue : 29-januari-2024

Survey : 2023-P4

Report : PFA 100/200

Note:
In the Survey Manual 2023 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.
This Survey Manual 2023 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 **March 13th, 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.

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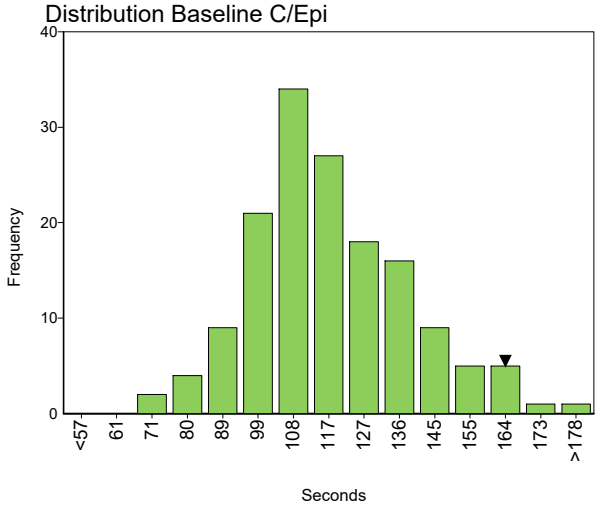
## PFA 100/200

PFA 100/200

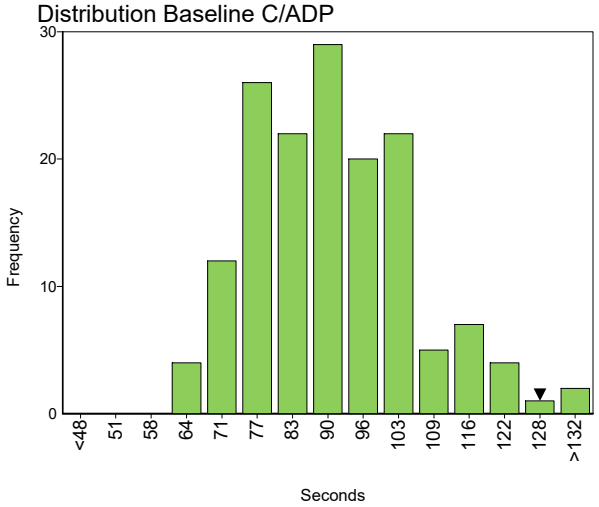
**Baseline results from donor native blood:**

| Test Parameter | Unit | n | Mean | Range | Own Result | Own Result | Own Result |
|---|---|---|---|---|---|---|---|
| Platelet Count | x10⁹/L | 135 | 245 | 94 - 424 | 256 | | |
| Mean Platelet Volume | fL | 118 | 9.8 | 6.5 - 14.0 | 9.9 | | |
| Haematocrit | L/L | 133 | 0.40 | 0.31 - 0.50 | 0.44 | | |
| VWF:AG | % | 61 | 123 | 47 - 220 | | | |
| VWF:RCo | % | 20 | 111 | 41 - 173 | | | |
| VWF:Activity | % | 42 | 129 | 42 - 295 | | | |
| VWF:CBA | % | 10 | 121 | 79 - 180 | | | |
| FVIII:C | % | 53 | 147 | 62 - 264 | | | |
| Baseline C/Epi | seconds | 152 | 117 | 70 - 192 | 165 | | |
| Baseline C/ADP | seconds | 154 | 90 | 63 - 149 | 127 | | |

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 | 1 | 1 | 0 | Normal | | |
| Mean Platelet Volume | 118 | 4 | 2 | 0 | Normal | | |
| Haematocrit | 128 | 6 | 0 | 0 | Normal | | |
| VWF:AG | 54 | 1 | 4 | 2 | | | |
| VWF:RCo | 19 | 0 | 1 | 0 | | | |
| VWF:Activity | 36 | 2 | 2 | 2 | | | |
| VWF:CBA | 10 | 0 | 0 | 1 | | | |
| FVIII:C | 44 | 3 | 5 | 2 | | | |
| Baseline C/Epi | 146 | 4 | 2 | 0 | Normal | | |
| Baseline C/ADP | 148 | 5 | 1 | 0 | Normal | | |

**Comments:**

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

| | | |
|---|---|---|
| **192** | (Mean Platelet Volume) | : 88.3 fL |
| **245** | (Platelet Count) | : 257000 / µL |
| **277** | (FVIII:C) | : 1.75% |
| **365** | (Mean Platelet Volume) | : 85 fL |
| **417** | (Mean Platelet Volume) | : 89.8 fL |
| **530** | (Mean Platelet Volume) | : 86.7 fL |
| **1274** | (Mean Platelet Volume) | : 84.7 fL |
| **1313** | (Mean Platelet Volume) | : 94.2 fL |
| **1352** | (Platelet Count) | : 226000 / mm^3 |
| **4561** | (Platelet Count) | : 270000 x 10^9 |
| **4567** | (Haematocrit) | : 4.07 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** | 23.237 |
| **Sample Details** | Normal PFA sample |
| **Prior Use** | None |
| **Unit** | seconds |
| **Expiry Date** | 02-februari-2025 |
| **Homogeneity** | - |
| **Homogeneity Parameter** | n.a. |
| **Number of Participants** | 174 |
| **Number of Responders** | 162 |
| **Response Rate** | 93 % |
| **Comments** | 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. Furthermore, two participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi and/or C/ADP cartridge. |

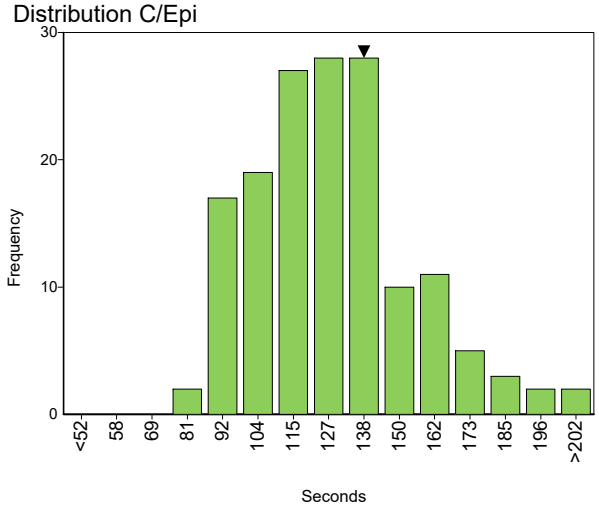
**Classification for sample 23.237:**

| Test Parameter | Normal | Borderine | Abnormal | No Classification | Own Result | Own Result | Own Result |
|---|---|---|---|---|---|---|---|
| C/Epi | 129 | 5 | 18 | 1 | Normal | | |
| C/ADP | 120 | 15 | 17 | 2 | Normal | | |

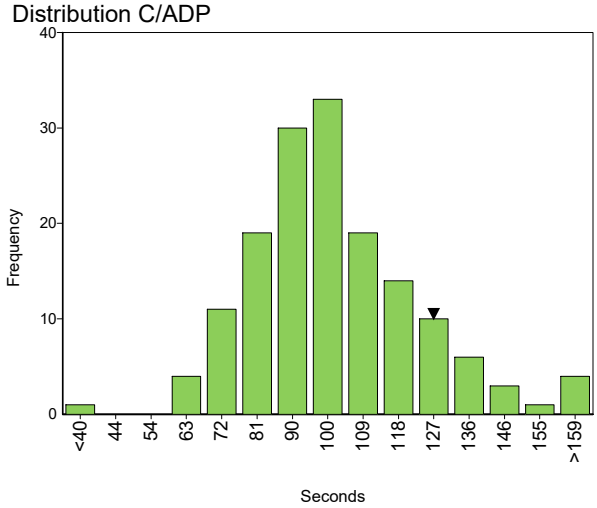
**Sample results:**

| Parameter | n | assigned value | Uncert. | CV (%) | range | your result | z-score | your result | z-score | your result | z-score |
|---|---|---|---|---|---|---|---|---|---|---|---|
| C/Epi | 154 | 127 | 2.5 | 19.7 | 77 - 234 | 143 | 0.64 | | | | |
| C/ADP | 155 | 100 | 2.0 | 20.0 | 37 - 300 | 125 | 1.28 | | | | |

Distribution C/Epi




Distribution C/ADP




**Final Conclusion:**

| | N |
|---|---|
| **Normal** | 122 |
| **Borderline** | 11 |
| **Mild Defect** | 9 |
| **Severe Defect** | 4 |
| **Aspirin-like Defect** | 9 |
| **Unable to Interpret** | 1 |
| **Test Failure** | 3 |
| **Other** | 1 |
| **No Conclusion** | 3 |

| | | |
|---|---|---|
| Normal | | |

**Conclusion Comments:**

About 75% of the participants correctly classified this sample as normal.
Surprisingly, about 13% 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** 23.238
**Sample Details** PFA sample with a mild defect
**Prior Use** None
**Unit** seconds
**Expiry Date** 02-februari-2025
**Homogeneity** 12.7 % **Homogeneity Parameter** C/Epi
For any method used for the measurement of this parameter with a **CV ≤ 42.3%** 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** 162 **Response Rate** 93 %
**Comments** 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, twenty-two participants reported a result above the upper limit of the measuring range [> (value)] for the C/Epi and/or C/ADP cartridge.

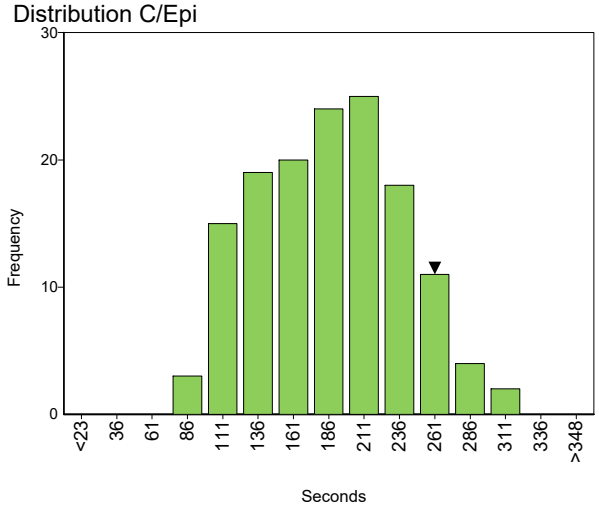
**Classification for sample 23.238:**

| Test Parameter | Normal | Borderine | Abnormal | No Classification | Own Result | Own Result | Own Result |
|---|---|---|---|---|---|---|---|
| C/Epi | 40 | 5 | 108 | 4 | Abnormal | | |
| C/ADP | 35 | 11 | 111 | 4 | Normal | | |

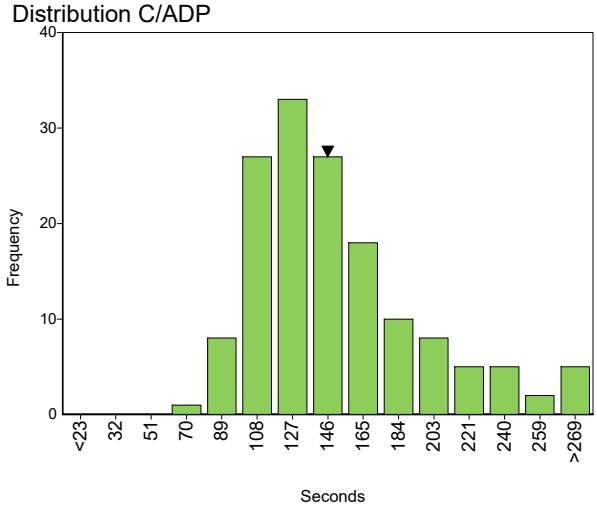
**Sample results:**

| Parameter | n | assigned value | Uncert. | CV (%) | range | your result | z-score | your result | z-score | your result | z-score |
|---|---|---|---|---|---|---|---|---|---|---|---|
| C/Epi | 141 | 186 | 5.7 | 29.1 | 82 - 300 | 254 | 1.26 | | | | |
| C/ADP | 149 | 146 | 4.2 | 28.2 | 76 - 300 | 137 | -0.21 | | | | |

Distribution C/Epi




Distribution C/ADP




**Final Conclusion:**

| | N |
|---|---|
| **Normal** | 25 |
| **Borderline** | 4 |
| **Mild Defect** | 46 |
| **Severe Defect** | 48 |
| **Aspirin-like Defect** | 22 |
| **Unable to Interpret** | 3 |
| **Test Failure** | 6 |
| **Other** | 1 |
| **No Conclusion** | 8 |

| | | |
|---|---|---|
| Aspirin-like Defect | | |

**Conclusion Comments:**

About 71% (n=116) of the participants classified this as sample with a defect. Forty percent (n=46) 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 15% (n=25) of the participants classified this sample with a mild defect as a normal sample!