Focus Article

External Quality Control for PFA 100/200

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Introduction

The PFA-100/200 is a test system for analysing platelet function in citrated whole blood. Blood is aspirated at high shear rates through disposable cartridges containing an aperture within a membrane coated with either Collagen and Epinephrine (CEPI) or Collagen and ADP (CADP). These agonists together with the high shear stress, induce platelet adhesion, activation and aggregation leading to rapid occlusion of the aperture and cessation of blood flow termed the closure time (CT). The PFA-100 is meant as a screening test to detect problems with primary haemostasis (platelet function, Von Willebrand Factor).

In 2019 a pilot study was performed on external quality control for the PFA 100/200. The meaning of this pilot study was to investigate the feasibility of such external quality control surveys.

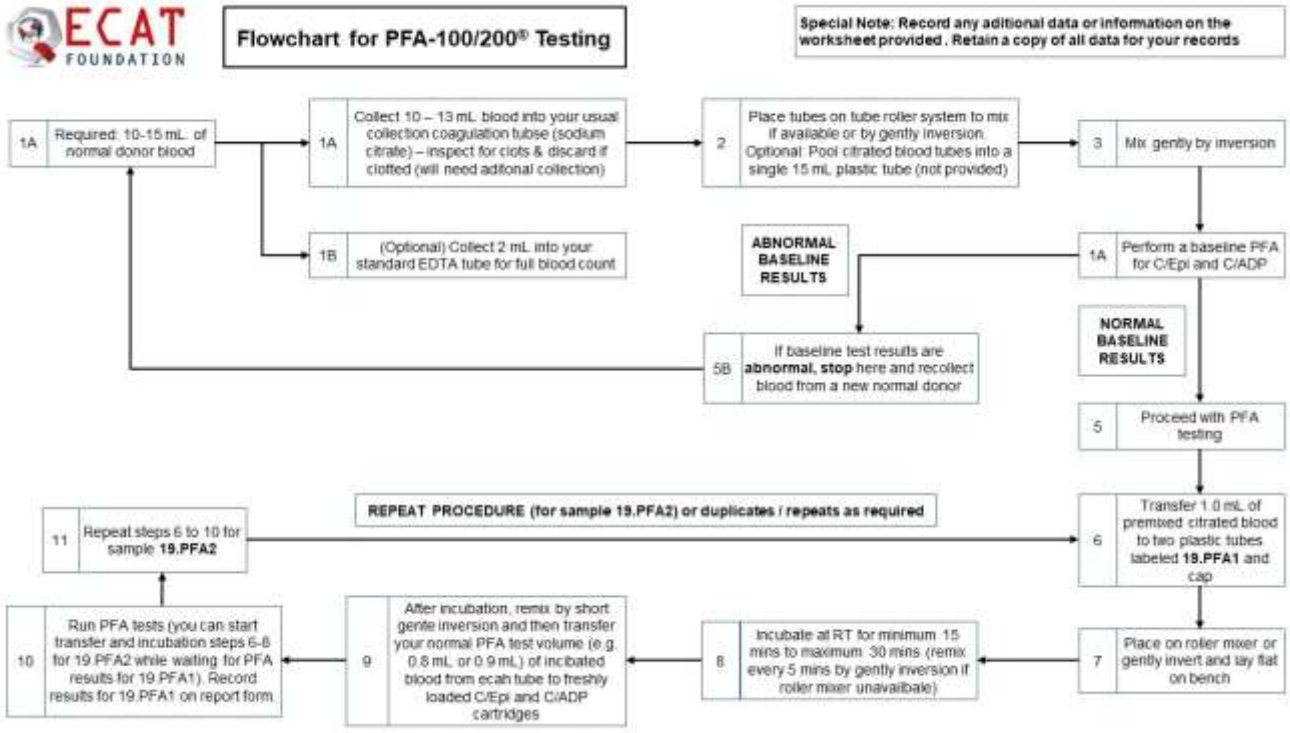
Set-up pilot study

In totally 75 different laboratories had indicated their interest in this pilot study. Fifty-five laboratories returned results.

In this pilot survey the following samples were used:

- Normal sample
- Severe defect (highly prolonged CTs for both type of cartridges)

The participants were asked to perform testing according to the below given flowchart:



Baseline results

Participants were asked to report basic test results for platelet count, haematocrit, Von Willebrand Factor parameters and Factor VIII of the normal donor blood. A summary of these results is given in the table below.

Parameter	N	Mean	Median	SD	Range
Platelet count (10^9/L)	53	247	252	42	155 - 354
Haematocrit	51	0.41	0.41	0.03	0.35 – 0.47
VWF:Ag (IU/dL)	36	114	124	31	46 – 194
VWF:RCo (IU/dL)	13	110	111	35	45 - 165
VWF:Act (IU/dL)	24	116	122	39	53 - 201
VWF:CBA (IU/dL)	7	127	134	46	54 - 192
FVIII (IU/dL)	36	138	139	39	67 - 248

The following baseline PFA test results were reported:

Parameter	N	Mean	Median	SD	Range	CV (%)
C/Epi (seconds)	55	115	109	25	77 - 234	21.7
C/ADP (seconds)	53	89	88	15	62 - 126	16.9

Reported reference ranges in the literature are for C/Epi between 74 and 191 seconds and for C/ADP between 57 and 152 seconds [1-3].
It can be considered that almost all reported results (99%) of the blood donors are within the expected range.

Results EQA samples

Normal Sample
The following results were reported for the normal sample:

Parameter	N	Mean	Median	SD	Range	CV (%)
C/Epi (seconds)	54	115	113	24.6	74 – 191	21.5
C/ADP (seconds)	54	98	97	20.9	57 – 178	21.3

The results of the normal sample were compared with the baseline results. This evaluation is given below:

Parameter	N	Mean Difference (sec)	Lower limit 95% CI	Upper limit 95% CI
C/Epi (seconds)	53	-1.1	-48.2	46.0
C/ADP (seconds)	52	- 9.4	-23.8	42.6

From these results it is clear that the vast majority of participants found a normal closure time for both cartridges.

Sample mimicking severe defect (highly prolonged CTs for both type of cartridges)
The following results were reported for the abnormal sample:

Parameter	N	Results
C/Epi (seconds)	55	Only 3 participants reported a numerical result: 49, 159 and 263 sec. Thirty-six participants reported a result above the maximum measuring limit (>value). The reported maximum measuring limits varied between 200 and 300 seconds. Sixteen participants reported a test failure.
C/ADP (seconds)	54	Only 3 participants reported a numerical result: 56, 97 and 117 sec. Thirty-seven participants reported a result above the maximum measuring limit (>value). The reported maximum measuring limits varied between 200 and 300 seconds. Fourteen participants reported a test failure.

Comments:

The majority of participants found a prolonged closure time for both the C/Epi and C/ADP cartridges. Three participants reported a numerical result for the C/Epi cartridge, which was a lower (49 vs. 111 sec.) or slightly higher (159 vs. 123 sec. / 263 vs. 234 sec.) closure time than their baseline result.

3 participants (one of these participants also found numerical results for the C/Epi cartridge) reported a numerical result for the C/ADP cartridge, which was a lower (56 vs. 88 sec.) or higher (97 vs. 63 sec. / 117 vs. 67 sec.) closure time than their baseline result.

From the results it is clear that the vast majority of participants found a strongly prolonged closure time for both cartridges, indicated a severe defect.

Conclusion

The ECAT Foundation has used in this pilot survey the same approach as that used by the RCPA in Australia [4]. Tubes with and without additives were distributed and participants had collected blood from a healthy donor. This blood was then measured by a PFA100/PFA200 analyser using C/Epi and C/ADP cartridges.

On the basis of this pilot study the ECAT Foundation has introduced surveys for external quality control for the PFA-100/200. If you are interested in this programme, please contact the ECAT office (info@ecat.nl)

References:

1. Akin, M. and Y. Polat, Platelet function analyser (PFA)-100 closure time in the evaluation of non-steroidal anti-inflammatory drug-induced platelet dysfunction in children with bleeding symptoms. Blood Transfus, 2012; 10: 545-6.
2. Mammen, E.F., P.C. Comp, R. Gosselin, C. Greenberg, W.K. Hoots, C.M. Kessler, et al., PFA-100 system: a new method for assessment of platelet dysfunction. Semin Thromb Hemost, 1998; 24: 195-202.
3. Cho, Y.U., S. Jang, C.J. Park and H.S. Chi, Variables that affect platelet function analyzer-100 (PFA-100) closure times and establishment of reference intervals in Korean adults. Ann Clin Lab Sci, 2008; 38: 247-53.
4. Favaloro, E.J. and R. Bonar, External quality assurance for the PFA-100(R). J Thromb Haemost, 2011; 9: 878-80.