PFA 100, PLATELET FUNCTION

Purpose

The purpose of this procedure is to provide instructions on how to perform platelet function analysis using PFA100.

Work place safety

All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.

- For standard precautions and safety practices in the laboratory; see LGM 8000, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
- For Universal Body Substance precautions, see LGM 8005, specifically, but not limited to, exposure to body fluids.
- For proper hand-washing, see LGM 8010, specifically, but not limited to, proper hand-washing.
- For proper infection control, see LGM 8004, specifically, but not limited to, proper use of gloves.
- For proper handling of regular and infectious waste, see LGM 8006, specifically, but not limited to proper disposal of regular and bio hazardous waste.
- For proper cleaning of work area, see LGM 8007 - Cleaning Work Areas.
- For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.

Principle

The PFA-100 is an instrument and test cartridge system in which the process of platelet adhesion and aggregation following a vascular injury is simulated in vitro. The PFA-100 can be used as an aid in the detection of platelet dysfunction in citrated human whole blood.

Specimen

Blue top tube with 3.2% or 3.8% buffered sodium citrate (1 part anticoagulant to 9 parts of blood). Use a 21G or larger needle to collect the sample. Mix sample by gently inverting tube 3 to 4 times by hand. Do not transport specimens by pneumatic tube system. Reject hemolyzed samples.

For Col./EPI test cartridge wait 10 min before testing the sample. All samples must be stored at room temperature and tested within 4 hours of collection.

Materials

PFA Collagen/Epinephrine (COL/EPI) test cartridge
PFA Collagen/ADP (COL/ADP) test cartridge
Test cartridges are good until expiration date when stored unopened at 2-8°C
Opened pouches are good for 90 days at 2-8 C. Cartridges stored at room temperature (16-26 C) are good for 4 hours
PFA Trigger solution (isotonic saline (0.9% aqueous sodium chloride)
Unopened trigger solution is stable at room temperature (16-26 C) until expiration date. Trigger solution on instrument is stable for 60 days.

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Quality Control

Follow the steps outlined below to perform QC. .

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Step	Action
1	Perform PFA-100 Self-test from the Maintenance Menu once per shift when instrument is in use and document it in the maintenance log..
2	Test a normal control donor in duplicate with each new shipment of cartridges and whenever you want to verify the performance of the system.
3	System is considered in control if the mean closure time of the normal control donor falls within the established normal reference range. Document results in the QC log.
4	If the mean closure time of the first normal control donor is outside the established reference range. Repeat testing with a second normal control. If the mean result of the second control donor.is within normal reference range the platelet function status and medication history of the first normal control donor should be suspected.
5	If the mean closure times form both donors are outside the reference range, contact the technical; solutions center
6	Do not continue testing until the problem has been resolved.
7	Document all corrective actions in the corrective action log.

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Procedure Refer to the PFA-100 Operating Manual for detailed operating instructions.

Step	Action
1	Perform a self-test from the Maintenance Menu at the start of each shift as part of QC practice
2	Test patients in singlicate. Test patients with CEPI cartridge first, if normal report in seconds if abnormal continue testing with CADP cartridge.
3	Allow pouch containing the CEPI test cartridges to warm-up to room temperature prior to opening and removing cartridges for test. This takes about 15min. After removal of the cartridge, close the pouch by using the re-closable seal.
4	Remove and discard the top foil seal from the cartridge. If the foil is missing or damaged, do not use the test cartridge. Place CEPI test cartridge in the cassette and push until the test cartridge securely snaps in place.
5	Sample loading, follow the next steps in sequence..
6	Mix the blood sample by inverting the collection tube gently by hand 3-4 times.
7	Hold the CEPI test cassette with the cartridge on a flat surface, pipette 800 µl of blood into the smaller opening (sample reservoir opening) of the test cartridge by dispensing slowly along on the inside corners. This will reduce the possibility of air entrapment in the sample reservoir.
8	Place the cassette with CEPI cartridge into the incubation well of the instrument so that the cassette is flush to the carousel surface.
9	Select run from the system ready display
10	Use numeric key pad or barcode reader to enter the patient ID (max 12 characters). To modify the patient ID, use the < to erase the ID and then re-enter the correct number
11	Press the soft key located next to RUN
12	When testing is complete, the instrument will print and display the results along with patients ID number. Results are reported by the instrument as Closure Time (CT) in seconds
13	.If the closure time is within normal reference range report result Report closure time in seconds.
14	If the closure time is abnormal continue testing with CADP cartridge following steps 2-12.
15	Dispose used cartridges into biohazard container. Note: Wear all protective equipment when disposing cartridges since there is a risk of exposure to aerosolized blood droplets when removing the test cartridges

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Results

Result CEPI in seconds if CEPI within normal range DNR CADP if CEPI abnormal report both CEPI and CADP in seconds

Interpretation of the results

The PFA-100 results must be analyzed in conjunction with all available information, such as history, physical examination, and other laboratory tests See below the basic interpretation and reporting.

- CEPI normal patient normal. Report CEPI result in seconds
- CEPI Abnormal, CADP Normal. Aspirin Effect Pattern. Report both CEPI and CADP results in seconds
- CEPI Abnormal, CADP abnormal. Platelet aggregation test of vWF work-up recommended. Report both CEPI and CADP in seconds.
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Limitations of the procedure

See a list of substances that may interfere with test results.

- Hemolysis (by reduction of Hct and release of ADP)s
- Certain fatty acids and lipids found in diets
- Platelet inhibiting agents, such as aspirin and anti-glycoprotein IIb/IIa antagonists, directly affect platelet functions
- Micro thrombi in the sample or particulates introduced into blood from environment could adversely affect test or cancel test due to flow obstructions.
- Many medications are known to affect platelet function. Therefore medication history of the patient needs to be reviewed
- Closure time above laboratory's cut-off could also be caused by Hematocrit <35% or platelet counts <150,000/ul..

Noncontrolled documents

See below

PFA-100 System: Getting Started Guide

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Reviewed and approved by:

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HISTORY PAGE

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Laboratory Director review/date	Laboratory Manager review/date	Date change implemented
New		12/6/12	12/11/12	12/6/12	