Sutter Health
Sutter Roseville Medical Center

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Owner:	*Alex Alba: Spvr, Laboratory*
Policy Area:	*Lab - Coag*
References:	
Applicability:	*Sutter Roseville Medical Center*

Operating the Platelet Function Analyzer, HC.ANA09.10-/-RV.xx

Purpose

This procedure describes how to perform sample analysis on the PFA-100

Equipment

A. PFA-100 Analyzer

Reagents

1. PFA Collagen/Epinephrine test cartridge

- Coated with equine collagen and epinephrine
- Test cartridges in unopened pouch are stable at 2-8 °C until the expiration date on label
- Test cartridges are stable for 30 days after opening the pouch when stored at 2-8 °C
- Test cartridges stored in an unsealed or sealed pouch are stable for up to 4 hours when stored at room temperature

2. PFA Collagen/ADP test cartridge

- Coated with Collagen and Adenosine Epinephrine
- Storage and stability the same as CEP test cartridge

3. Trigger solution

- 1 vial contains 11 ml of isotonic saline solution
- Trigger solution in unopened vial is stable at room temperature until expiration date on label
- ‡Trigger solution is stable for 60 days when placed on the analyzer
- ‡Discard trigger solution if particulate matter is visible

Specimen Requirements

- Whole blood collected in 3.2% buffered sodium citrate
- Specimens must be well mixed at the time of draw to prevent clotting
- Testing must be performed within 4 hours of collection
- Samples must not be centrifuged

- Samples must be maintained at room temperature
- When possible, samples should be collected using a 21 gauge needle or larger to prevent stimulation of platelet function
- Sample should be discarded if there is venous collapse or stoppage of blood flow during collection
- The presence of hemolysis may indicate poor sample collection and these samples should not be tested
- If a syringe technique is used, the sample must be anticoagulated within 30 sec of collection
- The blood should be drawn with minimal tourniquet time to avoid falsely elevating plasma vonWillebrand's factor through physiological release from the endothelium
- Samples should be checked for clots prior to testing and if detected must not be used

Quality Control

- Commercial QC material is not available for the PFA-100 analyzer
- For the purpose of QC testing, a normal control donor is used to assess the performance and "in control" conditions ofn the PFA-100
- Quality Control testing using a normal control donor (in duplicate) is performed on the PFA-100: 1) when a new lot of CEPI and/or CADP reagent or new shipment of CEPI and/or CADP reagent is received 2) when verifying system performance
- The normal control donor is tested in duplicate for both CEPI and CADP test cartridges
- The PFA-100 is considered "in control": 1) when the closure time (CT) in sec falls within established reference range for both CEPI and CADP results 2) the duplicate %CV is less than or equal to 15%
- Normal control samples that do not meet the above criteria should be repeated or a second normal donor sample collected and tested
- If the sample result from both normal donors do not meet the above criteria, then the test cartridge lot number may be suspect. Contact Dade Technical service at 1 800-242-3233

Procedure B - Running Quality Control Specimen

Step	Action
1	Remove test cartridges from the refrigerator and let warm at RT for 15-20 minutes.
2	Remove and discard the top foil seal from the test cartridges
3	Place the test cartridge into position "A" of the cassette. When running two tests, place the second test cartridge in position "B". the analyzer will automatically determine the test cartridge type before testing the sample
4	Mix blood gently by inverting by hand 3-4 times
5	Place the cassette with the test cartridge(s) on a flat surface, pipette 800 to 1000 ul of blood into the sample reservoir of the test cartridge by dispensing slowly along the inside corner. This will reduce the formation of air bubbles
6	Place the cassette with the test cartridges into the incubation well of the analyzer so that the cassette is flush with the carousel surface
7	Ensure screen is "System Ready" status. If not, press the softkey next to Menus until screen is displayed
8	Press the soft key located next to Run on the display screen
9	Use the numeric keypad to enter the control ID. If an ID is not entered, the analyzer will auto

	assign an ID and will begin testing
10	Press Run to start the testing
11	When testing is complete, the instrument will print and display the results along with the control ID and the type of test
12	Remove the cassette carefully from the carousel. Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge towards you until it unsnaps
13	Dispose of the test cartridge in a suitable biohazard waste container
14	If control values fall within established QC criteria, then proceed with patient testing. If control values do not meet established QC criteria, repeat the test using a different control donor sample. If problem persists, contact Dade Technical support

Procedure B - Running Patient Specimens

Step	Action
1	Prior to patient testing, samples are checked for low HCT/PLT values and hemolysis. Refer to "Limitations" section
2	Place one CEPI test cartridge in one of the two cassette positions
3	Mix blood gently by inverting by hand 3-4 times
4	Place the cassette with the test cartridge on a flat surface, pipette 800-1000 ul of blood into the sample reservoir of the test cartridge by dispensing slowly along the inside corner. This will reduce formation of air bubbles
5	Place the cassette with the test cartridge into the incubation wells of the analyzer so that the cassette is flush with the carousel surface
6	Ensure the "System Ready" screen is displayed. If not, press the softkey next to Menus
7	Press the softkey located next to Run on the display screen
8	Use the numeric keypad to enter the patient ID. To change patient ID, use the {<} key to erase then enter correct ID
9	Press Run to start testing
10	Review results: • If CEPI result is within established reference range then patient testing is complete and results are entered into LIS • If CEPI is out of reference range then run the CADP test cartridge and refer to steps 2 through 9 of procedure B
11	After each test, remove the cassette carefully from the carousel. Hold the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge towards you until it unsnaps
12	Dispose of the test cartridge in a suitable biohazard waste container
13	Enter results in the LIS

Interpreting Results

- Results of the PFA-100 are reported as Closure time (CT) in seconds. This closure time provides an indication of platelet function
- Results that fall outside the established reference range should be evaluated in conjunction with clinical and medication history

	Normal PLT function	Aspirin or medications which inhibit PLT function	Von Willebrand's disease	Glanzmann's thrombasthenia
CEPI	Normal	Abnormal	Abnormal	Abnormal
CADP	Normal	Normal	Abnormal	Abnormal

LIS Information

- Order is PFA
- Patient results are entered manually using the worksheet "RVKM"
- Control results are entered on the PFA control log
- The LIS canned text comments are the following

PFA 100 Result	LIS Comments
CEPI result normal	No comment attached
CEPI result abnormal and CADP result is normal	Abnormal CEPI with Normal CADP. This finding is usually associated with drug interference. Rule out ASA or other platelet inhibiting drugs
Both CEPI and CADP results are abnormal	Results suggests an inherent platelet dysfunction. Further investigation for platelet abnormalities or von Willebrand's disease is suggested if clinically indicated

Reference Range

- CEPI: 83 - 153 sec
- CADP: 57 – 110 sec

Critical Values

- CEPI: > 153 sec
- CADP: > 110 sec
- Critical results are called when both CEPI and CADP results exceed the upper limit of the normal range
- Critical call comment is attached to CADP result

Reportable Range

- CEPI: >300 sec
- CADP: >300 sec

Procedural Limitations

- Patient samples with hematocrits <20% and platelet counts <50 K/ul should not be tested
- Hematocrits <35 % and platelet counts <150 K/ul has been shown to cause prolonged closure times. In these cases, results are accepted and comment attached stating " The PFA test cannot distinguish between possible platelet dysfunction and abnormal low hematology results". Use the ETC PFAABN
- Hemolyzed samples should not be used. The lysis of red cells causes a reduction in the hematocrit and release of ADP which can result in falsely prolonged closure times
- Aspirin or medications such as ibuprofen,antibiotics, steroids, etc. directly affect platelet function. In addition, certain fatty acids and lipids are known to inhibit platelet function. A careful evaluation of the patient's medication history is recommended in cases of prolonged closure times
- Microthrombi or particulates in the sample could adversely affect the test results due to the obstruction of the sample flow
- Blood samples with high sedimentation rates may affect the test results. These samples should be run as single tests. If duplicate results are needed, then two separate runs should be performed
- Other hematological conditions that may interfere with testing include hyperviscosity syndromes, multilple myeloma, sickle cell disease, cold agglutinins, HCT's >50% and platelet counts >500,000. Further evaluations are needed for these clinical conditions
- Common error messages are listed below

Error Message	Explanation
Maximum time exceeded	The maximum CT (Closure time) for both CEPI and CADP is 300 seconds. Samples with platelet dysfunction will have this error code. Accept results if they correlate with clinical picture
Air leak	A vacuum leak may have occurred during testing due to a possible dirty O ring. Results are not valid. Perform a self test. If it passes, then repeat the test
Flow obstruction	This occurs when there are air bubbles or microthrombi in the sample. The results are not valid. Repeat the test. If the problem persists, the integrity of the sample should be questioned and the sample recollected
Maximum syringe travel reached	Commonly occurs in the presence of abnormal platelets. Repeat the test and accept the result

Related Documents

- Performing the Self Test on the PFA-100

References

- Dade Behring PFA-100 Operator's manual
- Test cartridge package inserts

All revision dates:

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Lindsey Westerbeck: Dir, Lab	pending