Beaumont HEALTH

Beaumont Laboratory
Royal Oak

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Related Documents:
RC.HM.CG.PR.002 Coagulation Tests: Reportable Limits and Normal /Therapeutic Values
RC.HM.CG.WF.001 Platelet Studies (PLT AGG and PFA) Workflow
RC.HM.CG.FRM.047e Platelet Studies (PLT AGG and PFA) Specimens Form

PLATELET FUNCTION ANALYSIS
DADE PFA-100™

RC.HM.CG.PR.027.r07

Principle

The DADE PFA-100™ platelet function analyzer uses whole blood flowing at a high rate of shear through an aperture in a membrane coated with a combination of collagen and epinephrine or collagen and ADP. This analyzer measures high shear Von Willebrand Factor (VWF) dependent platelet adhesion and aggregation. Blood flows through a defined aperture in a membrane coated with collagen and ADP (cartridge 1), or collagen and epinephrine (cartridge 2). Platelets stimulated by the collagen and agonist accumulate and plug the aperture causing blood flow to cease. The end point of the assay is closure time. Inhibited or diseased platelets will have an abnormally prolonged closure time. Drugs such as aspirin will prolong closure time of the collagen and epinephrine cartridge but not the collagen plus ADP cartridge. Patients with Bernard Soulier Syndrome (BSS), Glanzmann's Thrombasthenia and Von Willebrand's Disease (VWD) will show prolonged closure times with both cartridges.

Specimen Collection and Handling

Type	Two tubes of Whole blood collected in a 5 mL Hemogard vacutainer (2.7 mL draw).
Anticoagulant	3.2% sodium citrate
Amount	9:1 ratio (2.7 mL whole blood + 0.3 citrate) must be maintained. Tubes must be full.
Specimen Handling	**Specimens must NOT be sent through the pneumatic tube system!!!** **Do NOT spin sample! Whole blood is used for this analysis!**
Timing	Specimens must be kept at room temperature (20-25ºC) and analyzed within 4h of collection
Criteria for Unacceptable Specimens	Specimens containing clots, gross hemolysis or inappropriate volume are unacceptable and must be redrawn

Supplies/Equipment

DADE PFA-100™ Analyzer
PFA Vacuum Cartridge
PFA Priming Cartridge
PFA O-Ring Cleaning Pad

REAGENTS

1. **DADE PFA™ Collagen/Epinephrine (COL/EPI) Test Cartridge**: A test cartridge unit containing a membrane coated with 2 mcg of equine Type I collagen and 10mcg epinephrine bitartrate. Unopened pouches are stable at 2-8ºC until expiration date printed on the label. Test cartridges are stable up to 30 days after opening the pouch when stored at 2-8ºC. Test cartridges stored at room temperature (16-26ºC) in a sealed or unsealed pouch are stable for up to 4h.

2. **DADE PFA™ Collagen/ADP (COL/ADP) Test Cartridge**: A test cartridge unit containing a membrane coated with 2 mcg of equine Type I collagen and 50 mcg adenosine-5'-diphosphate (ADP). Unopened pouches are stable at 2-8ºC until expiration date printed on the label. Test cartridges are stable up to 30 days after opening the pouch when stored at 2-8ºC. Test cartridges stored at room temperature (16-26ºC) in a sealed or unsealed pouch are stable for up to 4h.

3. **DADE PFA™ Trigger Solution**: A trigger solution vial containing 11 mL isotonic saline (0.9% aqueous sodium chloride). Trigger Solution in unopened vial is stable at room temperature (16-26ºC) until the expiration date printed on the label. Trigger Solution is stable up to 60 days after the vial is placed on the instrument. Discard if turbid or if particulate matter is visible.

Quality Control

A. Self-Test

At least once per shift at the start of each shift that the system is in use, perform the PFA-100 "Self Test" from the "Maintenance Menu". Document on the appropriate log.

B. New Lot Number of Reagent

Per manufacturer's recommendations, controls must be run in duplicate on each instrument using a healthy donor from the established normal pool. The system will be considered under control if the mean closure time (CT) falls within the established reference range. If the mean CT is outside the reference range, repeat using a new healthy donor. If the mean CT's from both individuals are outside the reference range contact Technical Services. If the mean CT from the second individual is within the reference range, the platelet function status and medication history of the first individual should be suspected.

C. New Shipment of Reagent

New shipment may or may not be the same as current lot number.

A normal control (from established normal pool or healthy donor) should be run one time on each instrument with each new shipment of cartridges received or whenever there is need to verify the performance of the PFA instrument.

D. Normal donor control is performed weekly on active PFA 100.

NOTE: Individuals who are potential donors should be free from any medication known to affect platelet function.

Performance of this test is also monitored through participation in CAP proficiency surveys or equivalent.

PFA Correlations

1. A CV of ≤15% on the same instrument is acceptable for a normal platelet function test.
2. A CV of ≤15% between instruments is acceptable for a normal platelet function test.
2. There is no established allowable CV for abnormal platelet function tests.

Procedure

1. Remove test cartridges from refrigerator. Allow to come to room temperature for a minimum 15 minutes. After removal of the cartridges from the pouch, **close the pouch** by using the re-closeable seal. Cartridges may be at room temperature for up to 4h. If not used, cartridges may be returned to refrigerator. If at room temperature for more than 4h or if cartridges are exposed to heat, discard.

2. Collagen/Epinephrine cartridges will have one slot identifying them; Collagen/ADP cartridges will have 2 slots identifying them. You can place cartridges in either well (left or right) – instrument will identify cartridge type.

3. When handling cartridges, grasp by tab end opposite circular membrane area.

4. Open cartridges by carefully pulling back the foil covering the larger end. DO NOT touch area of large circle. If this area is disturbed, the membrane is punctured and test is invalid.

5. Carefully place the cartridge into the well. Snap it securely into place. The top of the cartridge should be flush with the top of the carousel.

6. Mix specimen by inverting tube gently 3-4 times. **Do not shake. Do not place specimen on tube rocker.**

7. Add at least 820-830 mcL well mixed whole blood to the smaller opening on top of each cartridge. Pipette blood slowly down side of opening. **Pipetting too fast will create air space at the bottom or air bubbles!**

8. On the instrument, select *"Run"*. The instrument will request identification of patient specimen. Enter patient order number. If the same patient specimen is in both cartridges, you need only enter number once and select *"Run Duplicate".* The instrument will assign the same I.D. number to both cartridges.

9. The test will take approximately 7-10 minutes.

10. When testing is complete, check specimen for clot .If present, cancel test. Results will be printed out on tape.

11. Remove cassette, discard cartridges into suitable biohazard waste container.

12. Replace cassette.

13. Enter results in LIS

Expected Values

NORMAL RANGE

Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.

REPORTABLE RANGE

Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.

INTERPRETATION OF RESULTS

Results of the PFA-100™ are reported by the instrument as Closure Time (CT) in seconds. The PFA-100™ test provides an indication of platelet function. Closure Time above the laboratory established cut-off may indicate the need for further diagnostic testing. Results should always be evaluated in conjunction with clinical history, presentation, and other laboratory findings (e.g. CBC and platelet aggregation). In cases where PFA-100™ results do not agree with the clinical assessment, additional tests should be performed.

If a test result has an error code message, for example, max test time, flow obstruction, or insufficient sample with a letter code after the result, see Attachment C for interpretations of the error codes.

Per pathologist, if you are aware that the patient's PLT count is <50,000bill/L, cancel the PFA.

If unable to achieve closure time on samples with low hematocrit (<30), cancel PFA due to low hematocrit.

Interfering Substances

1. Presence of hemolysis may interfere with test results:
   a. There may be a reduction in hematocrit (<35)
   b. There may be release of ADP.
2. Certain fatty acids and lipids found in various human diets are widely known to inhibit platelet function for which the PFA-100™ system was designed to detect. Neutral lipids, (e.g. cholesterol) generally have no effect on platelet function.
3. Platelet inhibiting agents directly affect platelet function.

Limitations

1. Microthrombi in the sample or particulates introduced into the sample from the environment may adversely affect the test results.
2. Samples exhibiting high sedimentation properties should be run as single tests. (Hemodynamic properties of the sample may be altered, potentially affecting the result.)
3. The medication history of the patient should be reviewed, since many medications are known to affect platelet function.
4. Results will be affected by patients with a low hematocrit (<35%) or decreased platelet counts (<150,000 bill/L).
5. Certain fatty acids and lipids found in various human diets are known to inhibit platelet function. Physicians may wish to advise patients to refrain from fatty foods prior to testing.

References

1. PFA-100™ Operating Manual. DADE International Inc., Miami FL 33172
2. DADE Behring PFA-100™ Reagents product insert. DADE International Inc., Miami FL 33172 November 1998.
3. PFA-100® Analyzer Getting Started/Training Guide. DADE BEHRING 2002, Lit Number H634.

Attachments

Attachment A – MAINTENANCE
Attachment B – ENTERING LOT NUMBERS/ PRINT QC RESULTS
Attachment C – GUIDE TO COMMON STATUS MESSAGES

Authorized Reviewers

Medical Director, Coagulation

ATTACHMENT A

MAINTENANCE

DAILY

SELF TEST – to be done daily, each shift of use.

1. From the System Ready display, press the softkey located next to [Menus].
2. From the Menu display, press the numeric key [2] to select the maintenance option.
3. Press the numeric key [2] to select the Self Test option.
4. Press the softkey located next to [YES] to continue the Self Test and follow the instructions displayed during the test.
5. Load a Vacuum Test Cartridge in Position A and B (insert a grayish blue Vacuum Test Cup into the blue Priming Cartridges). Press continue, the system will then rotate the carousel and instruct you to load the O-Ring Cleaning Pad (circular foam sponge) in the well. Once the cleaning pad is in position in the carousel well, add 4-5 drops of isopropanol alcohol to the center then press continue.
6. After the self tests are completed, the system will print the high/low flag ranges and the Pass/Fail results. If anything fails, repeat the Self Test. If it fails again, call Dade Behring Technical Support.
7. The system will prompt you to remove the O-Ring Cleaning Pad.
8. Remove the vacuum test cartridge from position B and inspect the trigger solution dispensing. Check that the trigger solution is dispensed on the raised platform of the vacuum cup. The size and exact centering of the drop is not critical. As long as there is a drop visible on the platform, trigger solution dispensing is adequate.
9. Remove the vacuum test cartridge from position A.
10. Remove the vacuum test cup from both cartridges and discard. Rinse both priming cartridges with distilled water and save for further use.

BI-MONTHLY (TWICE PER MONTH)

CLEAN O-RING

1. From the [System Ready] display, press the softkey located next to [Menus].
2. Press the number key [2] to select [Maintenance] option.
3. Press the numeric key [6] to select the [Remove O-Ring] option. The system will display the message [Load O-Ring Service Tool]. Place the O-Ring Service Tool into the incubation wells of the instrument so that the cassette is flush with the carousel surface.
4. Press the softkey located next to [Continue]. The system will rotate the carousel to the O-Ring removal position and bring the O-Ring in contact with Position “A” of the O-Ring Service Tool. After approximately 30 seconds, the carousel will rotate back allowing the removal of the O-Ring Service Tool.
5. Remove the O-Ring Service Tool and press the softkey located next to [Continue]. If the O-Ring Service Tool fails to remove the O-Ring, step 4 should be repeated once more. If the Service Tool fails to remove the O-Ring, contact the Dade Behring Technical Support.

6. Invert the O-Ring Service Tool and tap against the palm of your gloved hand to remove the O-Ring.
7. Rinse the O-Ring under running tap water. Place the O-Ring between forefinger and thumb and remove any debris by using a rubbing motion while rinsing under tap water. Visually inspect the O-Ring for debris or unusual wear and tear, such as cracks. If the O-Ring requires replacement, install a new O-Ring.
8. Shake excess water off O-Ring and soak in 70% isopropanol alcohol for 15 seconds.

INSTALL O-RING

1. From the [System Ready] display, press the softkey located next to [Menus].
2. Press the numeric key [2] to select [Maintenance] option.
3. Press the numeric key [7] to select the [Install O-Ring] option. The system will display the message [Load O-Ring Service Tool], then press [Continue].
4. Load O-Ring in Position "B" of the O-Ring Service Tool.
5. Place the O-Ring Service Tool into the incubation wells of the instrument so that the cassette is flush with the carousel surface.
6. Press the softkey located next to [Continue]. The system will rotate the carousel to the O-Ring removal position and bring the O-Ring in contact with the O-Ring Service Tool. After approximately 30 seconds, the carousel will rotate back, allowing the removal of the O-Ring Service Tool.
7. Remove the O-Ring Service Tool. Press [Continue].
8. Perform a [Self Test] to verify the system has no vacuum leak.

YEARLY

1. Each instrument is sent to Dade Behring for annual maintenance.
2. **REPLACE O-RING** – use procedure from bi-monthly maintenance

AS NEEDED MAINTENANCE

REPLACE TRIGGER SOLUTION

1. Pull up the knob to remove the probe from the trigger solution bottle and unlatch the access door. The door will automatically open when the knob is pulled to the top.
2. Remove the empty bottle.
   NOTE: It is normal that residual solution remains in the bottle.
3. Remove the flip-top cap and insert the new bottle.
4. Close the access door.
   NOTE: Be sure access door is fully closed before pushing the lever down to avoid damaging the trigger bottle spiking needle.
5. Push the knob all the way down to insert the probe into the trigger solution bottle.
   IMPORTANT: It is necessary to prime the system after replacing the trigger solution. Do not use trigger solution if turbid or if particulate matter is present.

PRIME SYSTEM

It is recommended to prime the system and run the Self Test after any extended (>2 days) period of non-use. This procedure will clear the system of any accumulated bubbles caused by the outgassing of the trigger solution.

1. Locate the priming cartridge provided for priming the system. (This cartridge is blue and does not have a top foil seal or a cup.) Snap the cartridge into the cassette. Use only one cartridge in either position A or B.
2. From the **System Ready** display, press the keypad next to *[Menus].*
3. Press *[2]* to select *Maintenance* option.
4. Press *[4]* to select *Trigger Prime* option.
5. Press keypad next to *[Prime]* to start priming the trigger solution. The cassette will rotate and the screen will display *"Trigger Priming, Please Wait".*
6. When priming is complete, the cassette will rotate to the load position. Remove the cartridge, discard the trigger solution accumulated in the cartridge during the priming cycle. Rinse the priming cartridge with distilled water. Save for future use or discard if damaged.
7. Press keypad next to *[Continue].*
8. Press keypad next to *[Previous Screen]* twice to return to the **System Ready** display.

REPLACE PRINTER PAPER

See Operator's manual.

REPLACE PRINTER RIBBON

See Operator's manual.

ATTACHMENT B

ENTERING LOT NUMBERS

1. From **System Ready** display, press keypad next to [Menus].

2. From Menu display, press [1] to select Run Control option.

3. Use the numeric keypad to enter the numeric portion of the lot number of the test cartridge being used. To modify the lot number use the [<] key to erase it, then enter the correct number. Press keypad next to [Enter].

PRINT CONTROL RESULTS

1. From **System Ready** display, press keypad next to *[Menus].*

2. From Menu display, press *[4]* to select *Print Log* option.

3. From Print Log display, press *[2]* to select *Control Results* option.

4. Use numeric keypad to enter the number of control results to be printed. Press keypad next to *[Enter]*. The system will print the number of results entered, starting with the most recent control performed.

ATTACHMENT C
GUIDE TO COMMON STATUS MESSAGES

1. Maximum test time exceeded (A)
2. Air leak (B)
3. Flow obstruction (C)
4. Insufficient sample (D)
5. Maximum syringe reached (E)

MAXIMUM TEST TIME EXCEEDED (A)	
Description	• The sample did not achieve closure of the aperture within the maximum time for a test (>300 seconds, not including the incubation period).
Causes	1. Sample with abnormal platelet function resulting in non-closure (NC) of the aperture. 2. A possible vacuum leak in the system causing a NC. 3. Defective test cartridge.
Solutions/Comments	1. If a NC is obtained with a normal donor control or the result does not agree with the patient's clinical history a possible vacuum leak may be suspected. Perform a Self Test via the Maintenance Menu without loading the O-ring cleaning pad. This will test if dirt or debris on the O-ring is the cause for the vacuum leak. If Self Test passes a defective cartridge may have caused the vacuum leak. If the vacuum leak test fails, perform the manual O-Ring maintenance procedure via the Maintenance Menu and rerun the Self Test. Cleaning or replacing the O-ring may correct the vacuum leak. If problem persists, contact Technical Assistance Center. 2. Rerun the sample with new cartridge to verify the test result. If daily Self Test OK then most likely this is an abnormal sample
Result Interpretation	• Report as CT >300 sec, abnormal platelet function as confirmed by retest.

ATTACHMENT C (STATUS MESSAGES) - continued:

TEST TERMINATED DUE TO AIR LEAK (B)	
Description	• The instrument has detected an initial air leak in the vacuum system. This condition is detected only at the beginning of a test.
Causes	• Possible vacuum leak in the system or a malfunctioning trigger solenoid pump. • No sample in test cartridge. • Air entrapped in fluid lines. • Air entrapped in test cartridge when sample was loaded • Defective test cartridge.
Solutions/Comments	• Verify that sample was added to test cartridge. Rerun the test with appropriate sample volume (820-830 μL). • Perform a Self-Test via the Maintenance Menu without the O-ring cleaning pad to test the vacuum system. If the vacuum test passes, a malfunctioning solenoid pump may be the cause for the air leak. Contact Technical Assistance Center for solenoid pump troubleshooting procedure. If the vacuum test fails, perform manual O-Ring maintenance procedure via the Maintenance Menu. Clean or replace O-Ring as per maintenance instructions. Perform Self Test. If vacuum leak test passes rerun sample. If problem persists contact Technical Assistance Center. • Prime system from Maintenance menu. • Rerun the test with a new cartridge and sample.
Result Interpretation	• Non-reportable.

ATTACHMENT C (STATUS MESSAGES) - continued:

TEST TERMINATED DUE TO FLOW OBSTRUCTION (C)	
Description	• The instrument has detected a sudden stoppage of blood flow during the test. A flow obstruction can occur at the start of a test or during a test run. Refer to the package insert (Limitations of Procedure section) for further information.
Causes	1. Initial flow Obstruction-This type of flow obstruction occurs when the instrument detects a failure to establish initial blood flow rate specifications subsequent to the first 30 seconds of testing. The instrument aborts the run if these specifications are not met. The result is reported as "Test Terminated Due to Flow Obstruction". This condition may be caused by microthrombi in the sample or particulates introduced into the sample or test cartridge from the environment. 2. Flow Obstruction During a Test – A flow obstruction that occurs after initial blood flow rate conditions have been established is reported by the instrument at the time the flow obstruction occurs; i.e. ">80C sec Flow Obstruction". This type of flow obstruction occurs when the capillary or the test cartridge membrane aperture is suddenly plugged by microaggregates that may form during the test or by particulates introduced into the sample or test cartridge from the environment. 3. Defective test cartridge.
Solutions/Comments	1. Verify that the sample does not contain clots or aggregates are visible, repeat once to rule out a defective cartridge. 2. A sample that results in repeated flow obstruction may have resulted from problems during blood collection. Recollect blood sample and repeat test. 3. If problem persists, contact Technical Assistance Center.
Result Interpretation	• Non-reportable.

ATTACHMENT C (STATUS MESSAGES) - continued:

TEST TERMINATED DUE TO INSUFFICIENT SAMPLE (D)	
Description	• The system has detected air being drawn subsequent to the first 30 seconds of testing. This condition is detected whenever the test runs out of sample and closure of the aperture has not occurred.
Causes	1. Not enough sample was loaded in the test cartridge. 2. Sufficient sample was loaded in the test cartridge but closure of the aperture did not occur due to platelet dysfunction and/or low sample viscosity (↓hematocrit, high sedimentation rate).
Solutions/Comments	1. Verify that 820-830 μL was added to the cartridge. Rerun sample using **900 μL**. 2. Verify sample hematocrit is within normal range. Refer to the package insert (Limitations of Procedure section) for further information. An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit will often induce this type of status message. Samples from patients treated with platelet antagonist drugs may exhibit characteristics that cause this type of status message. Adding additional specimen (up to 900 μL) could eliminate the insufficient sample message but a combination of low hematocrit and platelet dysfunction will most likely result in a closure time >300 sec. 3. The test cartridge cup serves as the receptacle where blood is collected after it passes through the membrane aperture. During a test, the instrument vacuum chuck interfaces with the cup and comes in close proximity to blood. Air that is drawn into the cup whenever an insufficient sample occurs can cause blood to foam and contaminate either the vacuum chuck or O-ring. It is recommended to perform manual cleaning of the O-ring with the cleaning pad to avoid potential contamination.
Result Interpretation	• An insufficient sample message that occurs at a time that is greater than the upper limit of the reference range may indicate abnormal platelet function due to the reasons stated above. In such cases this result may be reported as the time in which the test ended,”>xxx sec”, with a statement qualifying the properties of the sample (i.e. abnormal hematocrit and/or low platelet count) and suspicion of platelet dysfunction.

ATTACHMENT C (STATUS MESSAGES) - continued:

MAXIMUM SYRINGE TRAVEL (E)	
Description	• The system has stopped the current test because the syringe has reached the end of its travel prior to maximum test time.
Causes	1. Syringe piston moved too far too quickly as a result of low sample viscosity. Sufficient sample in the cartridge but closure did not occur due to platelet dysfunction and/or low viscosity (↓hematocrit high sedimentation rate). 2. A defective test cartridge causing a small vacuum leak. 3. Dirt or debris is present on the vacuum seal between the instrument and the test cartridge, causing a small vacuum leak. 4. Instrument malfunction causing a small vacuum leak.
Solutions/Comments	1. Perform a Self Test via the Maintenance menu without the O-Ring cleaning pad to rule out vacuum leaks. If no errors are reported by the Self Test the system is in control. 2. Verify sample hematocrit before performing a second test. If hematocrit is abnormal the sample may have low viscosity, which may induce platelet dysfunction. Refer to the package insert (Limitations of Procedure section) for further information. An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit will often induce this type of status message. Samples from patients treated with platelet GPIIb/IIIa antagonist drugs may exhibit characteristics that may induce this type of status message. Adding additional specimen (up to 900uL) could eliminate maximum syringe travel but will most likely result in a closure time >300 sec. If the repeat result confirms the abnormality, platelet dysfunction may be suspected possibly due to abnormal hemodynamic properties of the sample and/or antiplatelet agents. 3. If problem persists contact Technical Assistance Center.
Result Interpretation	• A maximum syringe travel message that occurs at a time that is greater than the upper limit of the reference range may indicate abnormal platelet function. The result may be reported as ">xxx sec" only if the time lies above the reference range. The report should include a statement qualifying the abnormal qualities of the sample and suspicion of platelet dysfunction.

PLATELET FUNCTION ANALYSIS – DADE PFA-100™

Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Beaumont Laboratory server:
S:\HEMACOAG\Document Control\Coagulation\Procedure\Master Documents\PFA
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 0
Location of circulating Controlled Copies: NA

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Sue Westley, MT(ASCP) Noelle Procopio, MT(ASCP)SH	01/2000			
Approved by: Joan C. Mattson, MD	01/19/2000			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Joan C. Mattson, MD	01/19/2000		New procedure.	
Joan C. Mattson, MD	11/28/2001		Retyped; no change.	
Joan C. Mattson, MD	10/08/2002		Updated control requirements.	
Noelle Procopio, MT(ASCP)SH	12/29/2003		No change.	
Joan C. Mattson, MD	01/02/2004		Updated interpretation of results error codes; clarified Appendix C.	
Joan C. Mattson, MD	08/20/2004		Added Interpretation of Results comments; added to Quality Control; added Reproducibility of Test Section; added PFA control.	
Noelle Procopio, MT(ASCP)SH	01/04/2005		No change.	
Joan C. Mattson, MD	02/08/2005	00	Standardized procedure format.	
Noelle Procopio, MT(ASCP)SH	12/22/2006		No change.	
Marc Smith, MD	12/18/2007	01	Clarified instrument correlation CVs; clarified specimen amount (Procedure), updated procedure format.	
Marc Smith, MD	04/30/2008	02	Added new self tests procedure; updated timing of specimen to 4h; eliminated reference to bleeding time; updated o-ring maintenance to bi-monthly; added CANC when PLT <50,000 bill/L.	
Marc Smith, MD	02/11/2009	03	Updated QC and correlations. Updated self tests.	

Marc Smith, MD	08/06/2010		No change	
Marc Smith, MD	06/07/2011		RC.HM added to SOP#; new format	
Marc Smith, MD	06/18/2013	04	Pg 4 Added CANCEL PFA due to low hematocrit (<30).	OK
Marc Smith, MD	03/03/2015		No change	OK
Marc Smith, MD	09/09/2015	**05**	Updated quality control section: clarified what to do for new shipment of cartridges; updated accession number to order number; updated frequency of self-test; added statement not to send through pneumatic tube system; updated related documents; attached attachments section to body of document.	OK
Marc Smith, MD	04/05/2017		No change	OK
	1/18/2018	**06**	Added Normal control is performed weekly PFA 100 on active instrument.	OK
Marc Smith,MD	03/30/2018	**07**	Added “check sample for clot” after test is complete and “enter results in LIS”	OK