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Platelet Function Analyzer Operation - Dearborn

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

- A. The purpose of this procedure is to provide guidance to the staff regarding the operation of the Platelet Function Analyzer (PFA).

II. PRINCIPLE:

- A. 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.
- B. The single use PFA-100 test cartridge consists of a capillary, a sample reservoir and a biochemically active membrane with a central aperture. The membrane is coated with collagen, generally believed to be the initial matrix for platelet attachment. The attachment of platelets to collagen is thought to trigger the initial physiologic stimulus for platelet activation. In addition, the membrane is coated with either epinephrine or ADP, which are other physiologic agonists.
- C. Anticoagulated whole blood is aspirated from the sample reservoir through the capillary and the aperture, which exposes platelets to high shear flow conditions. During the test, platelets adhere to the collagen-coated membrane; platelets become activated and release their granule contents upon contacting the agonist. The release is followed by adherence of platelets to each other to form aggregates. As a measure of platelet function in the PFA-100® system, the process of platelet aggregation and formation of a platelet thrombus at the aperture thereby gradually diminishes and arrests the blood flow. The PFA-100® instrument determines the time from the start of the test until the platelet plug occludes the aperture, and reports that time interval as the Closure Time (CT). The (CT) is an indicator of platelet function in the analyzed whole blood sample.

- D. The Collagen/Epinephrine (COL/EPI) Test Cartridge is the primary cartridge used to detect platelet dysfunction induced by intrinsic platelet defects, von Willebrand disease or exposure to platelet inhibiting agents. The Collagen/ADP (COL/ADP) Test Cartridge is used to indicate if an abnormal result obtained with the COL/EPI Test Cartridge may have been caused by the effect of acetyl salicylic acid (ASA) or medications containing (ASA).

III. CLINICAL SIGNIFICANCE:

- A. Patients with Bernard Soulier Syndrome (BSS), Glanzmann's Thrombasthenia and Von Willebrand's Disease (VWD) will show prolonged closure times with both cartridges.

IV. SPECIMEN COLLECTION AND HANDLING:

- A. All investigation of platelet function is strongly dependent on the correct method of blood collection. No special patient preparation is required.
- B. Venipuncture should be performed using a 21 G or larger needle, two tubes of blood should be drawn directly into an evacuated plastic or siliconized glass tube or syringe containing 3.8% (0.129M) or 3.2% (0.105M) buffered sodium citrate (1 part anticoagulant to 9 parts blood) - Blue citrate tube. Specimen collected with butterfly needle is not recommended. Use of unbuffered sodium citrate anticoagulant is NOT recommended. After sample collection, ensure proper mixing of anticoagulant by gently inverting the tube by hand 3 or 4 times.
- C. **Samples are to be hand delivered, not sent by the pneumatic tube system. Do not spin Sample-Whole blood is used for analysis. Discard the sample if there is a venous collapse or stoppage of blood flow during collection.**
- D. Specimens obtained from "line" draws must be free of heparin contamination.
- E. Label each specimen tube by following the patient identification policy with the patient name, medical record number, and date of birth.
- F. Record the date, and time of collection, and the identification of the person collecting blood specimen.
- G. CRITERIA FOR UNACCEPTABLE SPECIMENS:
1. Hemolyzed samples
 2. Specimens containing clots
 3. Inappropriate volume
- H. TIMING:
1. Patient samples are stable up to 4 hours and must be stored at room temperature undisturbed/unagitated.
 2. For the Col/EPI Test Cartridge, it is recommended that testing not be performed until 10 minutes after blood collection.
 3. Specimens must be kept at room temperature and brought to the department as soon as possible.

V. REAGENTS:

- A. Dade PFA[®] Collagen/Epinephrine (COL/EPI) Test Cartridge: A test cartridge unit containing a membrane coated with 2 mg of equine Type I collagen and 10 mg epinephrine bitartrate.
- B. Dade PFA[®] Collagen/ADP (COL/ADP) Test Cartridge: A test cartridge unit containing a membrane coated with 2 mg of equine Type I collagen and 50 mg adenosine-5'-disphosphate (ADP).
 - 1. Unopened pouches are stable at 2-8°C until expiration date printed on the label.
 - 2. Test cartridges are stable up to 90 days after opening pouch when stored at 2-8°C. Write the open date and expiration date on the outside of the pouch. If the expiration date is exceeded, discard the test cartridges.
 - 3. Test cartridges stored at room temperature (16-26°C) in a sealed or unsealed pouch are stable for up to 4 hours.
 - 4. Dade PFA[®] Trigger Solution: A trigger solution vial containing 11 mL isotonic saline (0.9% aqueous sodium chloride)
 - a. Trigger Solution in an unopened vial is stable at room temperature (16 to 26°C) until the expiration date printed on the label.
 - b. 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. Document open date and expiration date on vial.
 - c. These products are for in vitro diagnostic use only.

VI. EQUIPMENT:

- A. Dade PFA-100[®] Instrument

VII. SUPPLIES:

- A. PFA Vacuum Cartridge
- B. PFA Priming Cartridge
- C. PFA Ring Cleaning Pad
- D. O-Ring Service Tool
- E. 70% Isopropanol

VIII. MAINTENANCE:

- A. O-Ring Maintenance
 - 1. It is recommended to perform manual O-Ring cleaning on a weekly basis. The O-ring should be replaced on a yearly basis. The manual O-Ring cleaning procedure should be performed whenever the status message "VACUUM TEST FAIL" is obtained after a "Self-Test" is performed from the Maintenance menu or whenever the status message "TEST TERMINATED DUE TO AIR LEAK" is printed after a test.

2. Gloves must be worn when performing this cleaning procedure.
3. From the System Ready display, press the soft key located next to [MENUS].
4. Press the numeric key [2] to select the Maintenance option.
5. Press the numeric key [6] to select the Remove O-Ring option. The system will display the message "Load O-Ring Service Tool, then press "Continue."
6. Place the O-Ring Service Tool into the incubation wells of the instrument so that the cassette is flush to the carousel surface. Press the soft key 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.
7. Remove the O-Ring Service Tool and press the soft key located next to [CONTINUE].
8. 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 again, contact the Technical Assistance Center.
9. Invert the O-Ring Service Tool and tap against the palm of your gloved hand to remove the O-Ring.
10. Rinse the O-Ring under running tap water. Place 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, follow the install O-Ring option from the Maintenance menu to install a new O-Ring. Discard the old O-Ring in a suitable biohazard container.
11. Shake off excess water and soak in 70% isopropanol for approximately 14 seconds.
12. Shake off excess isopropanol.
13. From the System Ready display, press the soft key located next to [MENUS].
14. Press the numeric key [2] to select the Maintenance option.
15. Press the numeric key [7] to select Install O-Ring option. The system will display the message "Load O-Ring, Service Tool, then press "Continue."
16. Load O-Ring in Position "B of the O-Ring Service Tool. Place the O-Ring Service Tool into the incubation wells of the instrument so that the cassette is flush to the carousel surface. Press the soft key 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.
17. Remove the O-Ring Service Tool and press the soft key located next to [CONTINUE].
18. Perform a "Self Test" from the Maintenance Menu to verify that the system does not have a vacuum leak. When performing the "Self Test" to insure proper installation of O-Ring, it is not necessary to insert a cleaning pad when prompted, press continue to proceed with the "Self Test." Record Maintenance on the 'PFA Maintenance Log' worksheet.

19. If problems persist contact the Technical Assistance Center.
20. NOTE: To minimize dirt or debris accumulating on the O-Ring Service Tool, make sure the O-Ring placement surface (in position "B" of the O-Ring Service Tool) is free of debris before loading the O-Ring. If required clean the O-Ring placement surface with isopropanol.

IX. QUALITY CONTROL (QC):

- A. The PFA-100[®] Self Test from the Maintenance Menu should be performed once per shift at the start of each shift that the system is in use. Refer to the PFA-100[®] Operating Manual QC Procedures section for instructions. Instructions on how to establish the control donor group are given in the PFA[®]-100 package insert.
- B. As part of the instrument quality control, it is recommended to test in duplicate 2 control donors with each new shipment of cartridges received. The system will be considered under control if the mean closure time (CT) falls within the established reference range. (A healthy donor is someone that has not taken any medications known to affect platelet function in the last 2 weeks). If the mean CT is outside the established reference range, repeat this procedure with a second individual from the laboratory's established control donor group. If the mean CT's from both individuals are outside the reference range, contact the Technical Solutions Center. 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. These donor controls are stored at room temperature for up to 4 hours prior to testing. Quality Control should be performed under the following circumstances:
 1. Instrument set up.
 2. After preventative maintenance.
 3. New test cartridge lots.
 4. When an instrument problem is suspected.
- C. ENTERING LOT NUMBERS ON THE ANALYZER:
 1. From the System Ready display press keypad to [Menus].
 2. From the 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 and enter the correct number.
 4. Press keypad next to [Enter].
- D. PRINT CONTROL RESULTS FROM THE ANALYZER:
 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 the numeric keypad to enter the number or control results to be printed.
 5. Press the keypad next to [Enter]. The system will print the number of result entered,

starting with the most recent control performed.

E. RECORD QC RESULTS

1. Record results of QC on the 'PFA Cartridges QC Log' worksheet.

F. MONTHLY REVIEW:

1. The supervisor or designee will review the PFA test records for the current month. This review will include all three components of the test system: including the analytic and post-analytic components.
2. Monthly metrics will be reviewed with the acceptable compliance of 100%.
3. Variance from this will require investigation.
4. NOTE: Performance of this test is also monitored through participation in CAP proficiency surveys.

X. PROCEDURE:

- A. Hematology should receive a phone call from the phlebotomist that a PFA has been drawn; samples are to be hand delivered.
- B. Remove test cartridges from the refrigerator.
- C. Prime trigger before every patient.
- D. Verify open date of Test Cartridge Pouch.
- E. If the pouch has been opened longer than 3 months, discard the cartridges.
- F. Allow the cartridges to come to room temperature for a minimum 15 minutes.
- G. After removal of the cartridges from the pouch, be sure to reseal the pouch securely.
- H. Cartridges may be at room temperature for up to 4 hours.
 - I. If not used, cartridges may be returned to refrigerator.
- J. If at room temperature for more than 4 hours, or if cartridges are exposed to heat, they must be discarded.
- K. When handling cartridges, grasp by tab end opposite circular membrane area.
- L. 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 may be punctured and test would be invalid.
- M. Carefully place the EPI (1 slotted) cartridge in position "A" (the left side) of the testing carousel.
- N. Place the ADP (2 slotted) cartridge in position "B" (the right side) of the testing carousel.
- O. The top of the cartridge should be flush with the top of the carousel.
- P. Mix specimen by inverting tube gently 3-4 times. Do not shake or place specimen on tube rocker.
- Q. Add 800 µl well mixed whole blood to the smaller opening on top of each cartridge.
- R. If the patient's hematocrit is less than 35%, the volume may be increased to 900µl.

- S. Slowly pipet sample, pipetting too fast will create air space, or air bubbles at the bottom.
 - 1. NOTE: The specimen must be pipetted into cartridge and loaded on instrument before entering patient information. Once "RUN" is selected, cartridges become inaccessible.
- T. Select "Run". DO NOT select Run if sample has not been pipetted yet, the cartridges will be ruined.
- U. The instrument will request identification of patient specimen.
- V. Enter specimen's container identification number. If the same patient's specimen is in both cartridges you need only enter the number once; select "RUN DUPLICATE", the instrument will assign the same I.D. number to both cartridges.
- W. Select "Run". The test will take approximately 7-10 minutes.
- X. When testing is complete, the results will be printed out on the paper tape.
- Y. Verify that the results on the paper tape match the results interfaced to the Laboratory Information System (LIS).
- Z. Results falling outside of the reference range may need to be manually verified in the LIS.
- AA. Record patient results on the 'PFA Patient Result Log Sheet'

XI. REPORTING RESULTS:

- A. Results of the PFA-100[®] test are reported by the instrument as Closure Time (CT) in seconds.
- B. These results should be related to the reference interval for each cartridge type. See Section XII. Expected Values.

XII. EXPECTED VALUES:

- A. REFERENCE RANGE:
 - 1. Collagen/Epinephrine: 78 – 141 seconds
 - 2. Collagen/ADP: 66 – 107 seconds
- B. INSTRUMENT REPORTABLE RANGE:
 - 1. Collagen/Epinephrine: 0-300 seconds
 - 2. Collagen/ADP: 0-300 seconds

XIII. INTERPRETATION OF RESULTS:

- A. Results of the PFA-100[®] test are reported by the instrument as Closure Time (CT) in seconds. The PFA-100[®] test provides an indication of platelet function.
- B. Closure Time above the laboratory established cut-off may indicate the need for further diagnostic testing.
- C. Platelet dysfunction detected by the PFA-100[®] system may be acquired, inherited, or induced by platelet inhibiting agents. The most common causes of platelet dysfunction are related to

uremia, von Willebrand disease (vWD), and exposure to agents, such as acetyl salicylic acid (ASA, for example Aspirin®).

- D. As expected, platelet plug formation in the PFA-100® system is affected by low platelet count and/or activity, inadequate plasma von Willebrand factor status, and additionally by, inadequate hematocrit because of the flow process.
- E. Results should always be evaluated in conjunction with clinical history and other laboratory findings (such as platelet aggregometry). In cases where PFA-100® results do not agree with the clinical assessment, additional testing should be performed.
- F. The following are expected patterns observed with the PFA test on normal subjects and subjects with various disorders:

	Normal	ASA	vWD	Glanzmann's thrombasthenia
COL/EPI	normal	prolonged	prolonged	prolonged
COL/ADP	normal	normal	prolonged	prolonged

XIV. LIMITATIONS:

- A. Presence of hemolysis may interfere with test results. The presence of free hemoglobin from lysis of red cells could affect the PFA-100 closure time for two reasons, reduction in hematocrit (less than 35%) or release of ADP.
- B. Certain fatty acids and lipids found in various human diets are widely known to inhibit platelet function, which the PFA-100 system was designed to detect. Physicians may wish to advise patients to refrain from fatty foods prior to testing. Neutral lipids, such as cholesterol, generally have no effect on platelet function.
- C. Platelet inhibiting agents, such as aspirin and anti-glycoprotein IIb/ IIIa antagonists, directly affect platelet function.
- D. Microthrombi in the sample or particulates introduced into the sample from the environment could adversely affect the test results and/or cause a cancellation of the test by the instrument due to the detection of a flow obstruction.
- E. Blood samples with high sedimentation properties may experience some settling in position B while waiting to be tested. Should settling occur, the hemodynamic properties of the sample may be altered, potentially affecting the result. Thus, it is recommended that samples exhibiting high sedimentation properties be run as a single test. In order to obtain duplicate measurements, two separate runs should be performed.
- F. Many medications are known to affect platelet function. Therefore, the medication history of the patient should be reviewed by the physician.
- G. Closure Time above the laboratory cut-off could reflect reduced platelet function caused by hematocrit < 35% or platelet counts < 150,000/mL. Specimens with hematocrit levels >50% or platelets counts >500,000/mL have not been evaluated.
- H. If the PFA-100® system cannot be made to operate properly, credit the test with message "Unable to perform test due to Instrument error". Call floor and notify then document in the LIS.

XV. COMMON STATUS MESSAGES:

- A. Maximum test time exceeded (A)
- B. Air leak (B)
- C. Flow obstruction (C)
- D. Insufficient sample (D)
- E. Maximum syringe reached (E)
- F. MAXIMUM TEST TIME EXCEEDED (A):
 - 1. Description: The sample did not achieve closure of the aperture within the maximum time for a test (>300 seconds, not including the incubation period).
 - 2. Causes: Sample with abnormal Platelet function resulting in non-closure (NC) of the aperture.
 - 3. Solutions/Comments:
 - a. 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 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.
 - 4. Results Interpretation: Report as CT >300 sec, abnormal platelet function as confirmed by retest
- G. TEST TERMINATED DUE TO AIR LEAK (B):
 - 1. Description: The instrument has detected an initial air leak in the vacuum system. This condition is detected only at the beginning of a test.
 - 2. Causes:
 - a. Possible vacuum leak in the system or a malfunctioning trigger solenoid pump.
 - b. No sample in test cartridge.
 - c. Air entrapped in fluid lines.
 - d. Air entrapped in test cartridge when sample was loaded.
 - e. Defective test cartridge.
 - 3. Solutions/Comments:
 - a. Verify that sample was added to the test cartridge. Rerun the test with appropriate sample volume.
 - b. Perform a Self-Test via the Maintenance Menu without the O-ring cleaning pad to test the vacuum system.

- c. If the vacuum test passes, a malfunctioning solenoid pump may be the cause for the air leak. Contact Technical Assistance Center for solenoid pump trouble shooting procedure.
- d. 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.
- e. If vacuum leak test passes rerun sample. If problem persists contact Technical Assistance Center.
- f. Prime system from Maintenance menu.
- g. Rerun the test with a new cartridge and sample.

H. TEST TERMINATED DUE TO FLOW OBSTRUCTION (C):

1. 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 (Limitation of Procedure section) for further information.
2. Causes:
 - a. 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". The condition may be caused by microthrombi in the sample or particulates introduced into the sample or test cartridge from the environment.
 - b. 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.
Defective test cartridge

3. Result interpretation: Non-reportable

I. TEST TERMINATED DUE TO INSUFFICIENT SAMPLE (D):

1. 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 occurred.
2. Causes:
 - a. Not enough sample was loaded in the test cartridge.
 - b. 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 (low hematocrit, high sedimentation rate).

3. Solutions/Comments:

- a. Verify that 800 μ l was added to the cartridge. Rerun sample using 900 μ l.
 - b. 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 μ l) could eliminate the insufficient sample message but a combination of low hematocrit and platelet dysfunction will most likely result in closure time >300 seconds.
 - c. The test cartridge cut serves as the receptacle where blood is collected after it passes through the membrane aperture. During a test the instrument vacuum check interfaces with the cup and comes in close proximity to the blood. Air that is drawn into the cup whenever an insufficient sample occurs can cause blood to foam and contaminate either the vacuum check or O-ring. It is recommended to perform manual cleaning of the O-ring with the cleaning pad to avoid potential contamination.
4. Results 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.

J. TEST TERMINATED DUE TO MAXIMUM SYRINGE TRAVEL (E):

1. Description: The system has stopped the current test because the syringe has reached the end of its travel prior to maximum test time.
2. Causes:
 - a. Syringe piston moved too far too quickly as a result of low sample viscosity.
 - b. Sufficient sample in the cartridge but closure did not occur due to platelet dysfunction and/or low viscosity (low hematocrit, high sedimentation rate).
 - c. A defective test cartridge causing a small vacuum leak.
 - d. Dirt or debris is present on the vacuum seal between the instrument and the test cartridge, causing a small vacuum leak.
 - e. Instrument malfunctioning causing a small vacuum leak.
3. Solutions/Comments:
 - a. 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.

- b. Verify sample hematocrit before performing a second test.
 - c. If the 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 a 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 900 µl) could eliminate maximum syringe travel but will most likely result in a closure time >300 seconds. 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.
 - d. If problem persists contact Technical Assistance Center.
4. Results 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 seconds” 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.

XVI. NOTES:

- A. All blood samples and blood components should be treated as potentially infectious.
- B. All samples should be handled in accordance with good laboratory practices using appropriate precautions. Personal protective equipment should be worn when inserting or removing cartridges from the carousel.
- C. To avoid injury, do not disassemble the test cartridge.
- D. The PFA-100® is incapable of detecting bubbles in the test cartridge.
- E. There is a risk of exposure to aerosolized blood droplets when removing the test cartridges.
- F. Error message interpretation can be found in the Siemens Operator’s Manual starting on page 25. If Error D (Test Terminated Due to Insufficient Sample) occurs, check CBC parameters listed in #7 of Limitations on page 144. Repeat test using 900 µL. If the error message recurs, report the time at which the test ended along with language describing the properties of the sample. Example: > 138 sec -; platelet count is < 150,000/µL.; Platelet dysfunction cannot be ruled out.

XVII. REFERENCES:

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12. Dade-Behring PFA-100[®] Operator's Manual

Attachments

[PFA Cartridges QC Log.pdf](#)

[PFA Maintenance Log 080223.pdf](#)

[PFA Patient Result Log Sheet.pdf](#)

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	8/30/2023

Policy and Forms Steering
Committee Approval (if
needed)

Lilly Reid: Medical
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8/28/2023

Helga Groat: Supv, Laboratory

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Kimberly Geck: Dir, Lab
Operations B

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8/27/2023

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