TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	8/3/2016
Department:	Core	**Due Date:**	8/31/2016
		Implementation:	**9/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Platelet Function - PFA-100 SGAH.G03 v3

PFA100 Lot To Lot Cross Check Log AG.F120.4
PFA-100 Establishment of Control Donor Group Data Form AG.F118.2

Description of change(s):

Section	Reason
Header	Add WAH
2	Update wording
3.1	Add a statement on venous collapse and or stoppage during blood collection
6.1	**Add details on control donor group**
6.3	**Clarify QC frequency**
6.4	Add control group limits
6.6	Add control group documentation
6.7	**Add detail for lot to lot check**
8.1	Specify by shift, add expiration date
8.3	Reword steps 4 and 6
10.1	Add result interpretation statement
10.5	Add detail to resolve error messages
11.3	Add report comment
14.2	Add statement on precision
14.4	Update sensitivity
19	Add Addendum B

Lot to Lot Cross Check Form has been re-formatted and has a new formula and acceptance criteria using TEA

Control Donor Group Form – removed requirement to test in duplicate and to calculate %CV. A list of donors will be maintained in QC books for easy access.

The revised SOP & FORMS will be implemented on September 1, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Platelet Function - PFA-100**
Prepared by	Ashkan Chini Date: 6/9/2011
Owner	Robert SanLuis Date: 6/9/2011

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Platelet Function Analysis	PFA-100	CEPI, CADP

Synonyms/Abbreviations
Closure Time (CT); Collagen/Epinephrine (COL/EPI); Collagen/ADP (COL/ADP)

Department
Coagulation

2. ANALYTICAL PRINCIPLE

The PFA-100 is a system for analyzing platelet function in which citrated whole 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 induce platelet adhesion, activation and aggregation leading to rapid occlusion of the aperture and cessation of blood flow termed the closure time (CT).

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	Blood samples should be obtained from an extremity free of peripheral venous infusions. Collection of blood sample should be performed with care to avoid contamination by tissue factors.
Special Collection Procedures	• Use a 21 gauge or larger needle. A 21 gauge Butterfly may also be used. • First, collect a discard tube (one blue top tube, at least 2 mL). If patient has additional tests ordered, always draw the required tubes for this test first to avoid any contamination. • Fill the sample tube to the black line printed half way on the tube. Do not under fill. • Discard the sample if there is a venous collapse or stoppage of blood flow during collection. • Collect two tubes per patient. • Gently invert the tube at least 5 times to ensure complete mixing of the contents.
Other	Do not place the sample in a water bath or on a rocker plate. Do not centrifuge the samples. Samples must be hand delivered to laboratory. Do not use the pneumatic tube system.

3.2 Specimen Type & Handling

Criteria		
Type	**-Preferred**	Whole Blood
	-Other Acceptable	None

Form revised 2/02/2007

Criteria	
Collection Container	Preferred: Greiner Bio-One partial-fill vacuette tube with 3.2% sodium citrate Other acceptable: Light blue top tube with 3.2% sodium citrate (9:1 blood to anticoagulant)
Volume - Optimum **- Minimum**	2 - 2 mL Greiner Bio-One tubes 1 - 2 mL Greiner Bio-One tubes
Transport Container and Temperature	Collection container tube at room temperature.
Stability & Storage Requirements	Room Temperature: 4 hours (18 - 25°C)
	Refrigerated: Unacceptable
	Frozen: Unacceptable
Timing Considerations	Blood must equilibrate at room temperature for a minimum of 10 minutes after collection before testing.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Clotted or under-filled tubes are not accepted. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message.
Compromising Physical Characteristics	Clotted and/or hemolyzed specimens are unacceptable. Reject sample and request a recollection. Credit the test with appropriate LIS English text code HMM (Specimen moderately hemolyzed) or HMT (Specimen markedly hemolyzed)
Other Considerations	Fresh whole blood samples are required for this test.

4. REAGENTS

Refer to the Safety Data Sheet (SDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
PFA-100® Collagen/EPI Test	Siemens, Cartridge, Cat. No. B4170-20A
PFA-100® Collagen/ADP Test	Siemens, Cartridge, Cat. No. B4170-21A
PFA-100® Trigger Solution	Siemens Cat. No. B4170-50
Isopropanol 70%	Fisher Scientific A459-1

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Safety Data Sheet (SDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit	
Collagen/EPI Test Cartridge	A test cartridge unit containing a membrane coated with 2 µg of equine Type I collagen and 10 µg epinephrine bitartrate.
Collagen/ADP Test Cartridge	A test cartridge unit containing a membrane coated with 2 µg of equine Type I collagen and 50 µg adenosine-5 diphosphate.
Container	Unopened pouch.
Storage & Stability	Cartridges in an unopened pouch are stable at 2-8° C until expiration date printed on the label. After opening the pouch, cartridges are stable up to 3 months when stored at 2-8° C. Cartridges are stable up to 4 hours at room temperature.
Preparation	Allow the pouch containing the test cartridges to warm up to room temperature (16-26° C) for 15 minutes.

PFA Trigger Solution	Vial contains 11 ml isotonic saline (0.9% aqueous sodium chloride).
Container	Manufacturer supplied vial
Storage & Stability	Unopened vial is stable at room temperature (16-26ºC) until the expiration date printed on the label. Once the vial is placed on the instrument it is stable up to 60 days. Discard if turbid or if particulate matter is visible.
Preparation	None

Isopropanol	70% Isopropyl Alcohol
Container	Manufacturer supplied vial
Storage & Stability	Opened or unopened product is stable until the expiration date stamped on the vial.
Preparation	None

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

- PFA-100® "Self Test"
- Control Donor Group
  - Each laboratory needs to establish its own control donor group; these individuals must not have Von Willebrand disease and should not be taking any medications (specifically Aspirin) that inhibit platelet function. Refer to addendum B for medication list.
  - Donors are qualified for a 6 six month period. If the donor qualification period has expired the donor must have their platelet function verified as normal (or acceptable for use in the donor control group). New donors can be tested and qualified as acceptable on any "in-use" reagent lot number.
  - In the event of a supply back order issue, only a pre-approved donor, qualified within the last 6 months, can be used to verify a new reagent lot number.
  - Testing is documented on the "PFA-100 Control Donor Group Data Form"; an acceptable range is set up using the reference ranges; the average plus or minus 1.5 standard deviation. (The comment section on the donor group log is to document the reason for testing or to note the exclusion of a potential donor).

6.2 Control Preparation and Storage

N/A

6.3 Frequency

- **PFA-100 Self Test is performed once per shift** and any time the instrument is turned off/on.
- The Control Donor Group will be analyzed on a semi-annual basis to ensure the individuals remain within acceptable limits.
- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with an individual from the Control Donor Group.
- After major repairs (instrument sent out for repair) or upon receipt of a loaner instrument, testing must be performed using an individual from the Control Donor Group.

6.4 Tolerance Limits

PFA-100 Self-Test
The Self-Test must pass all internal parameter checks and external inspection criteria (refer to section 8.2, steps 10 - 13).

IF the Self-Test fails …	THEN…
First Time	Turn the instrument OFF then ON to reset the instrument
Second Time	Remove O-Ring via the maintenance menu. Inspect O-Ring for dirt, debris or damage. Clean or replace O-Ring if required. *(Changing the O-Ring is considered routine maintenance)*
Third Time	If problem persists, contact technical assistance center

Control Donor Group
Acceptable range is established using the reference ranges; the average plus or minus 1.5 standard deviation.

Collagen/Epinephrine: 106 – 181 Seconds
Collagen/ADP: 77 – 112 Seconds

Results are recorded on the PFA-100 Control Donor Group Data Form

6.5 Review Patient Data

Each result is reviewed for error messages. Refer to the PFA – 100 system manual "Error messages" section for troubleshooting. Resolve any problems noted before issuing patient reports.

6.6 Documentation

- Document Self-Test results on the PFA-100 QC/Maintenance log.
- Record semi-annual Donor Control Group testing on the PFA-100 Control Donor Group Data Form
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of test cartridges or new shipment of the same lot of test cartridges must be tested with "Control Donor Group". Performance of the new lot must be equivalent to the previous lot. Testing is run in duplicate and results averaged. TEA between old and new lots is calculated and must be less than or equal to 25%. Refer to PFA100 Lot To Lot Cross Check Log.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.

- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens PFA-100® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C

7.3 Supplies

- 800 - 1,000 µL pipette or equivalent
- Appropriate pipette tips
- O-ring cleaning pads, Cat. No B4170-73
- Priming cartridges, Cat. No B4170-74
- Vacuum test cups, Cat No. B4170-75
- O-ring service tool, Cat. No B4170-77
- O-rings, Cat. No. B4170-78
- Printer ribbon, Cat. No. B4170-72
- Printer paper

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-up Protocol
1.	Perform Self-Test on each shift.
2.	Check Trigger solution for volume, expiration date, and possible contamination.
3.	Check printer paper, replace if necessary.
4.	Weekly: Clean and inspect the O-Ring.

8.2	Performing a Self-Test
1.	From the system ready display, press the soft key located next to “Menu”.
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

8.2	Performing a Self-Test
4.	Place priming cartridges (blue color) into both positions A and B of gray cassette. Then load a vacuum test cup in each cartridge.
5.	Press the soft key located next to "YES" to continue the self-test and follow the instructions displayed during the test.
6.	The system will then rotate the carousel and instruct you to load the O-Ring cleaning pad (circular foam sponge) into the well.
7.	Once the cleaning pad is in position in the carousel well apply 4 - 5 drops of 70% Isopropanol alcohol to the center of the pad. Press gently on the pad with a gloved index finger 2 – 3 times to help distribute the alcohol. **Note**: use a new cleaning pad, and a new Vacuum Test cup with each self-test
8.	Press the soft key located next to "Continue".
9.	The PFA-100 will perform the O-Ring cleaning procedure and a Vacuum Test in addition to the power on diagnostics tests. The system will print the Pass/Fail results as each test is completed.
10.	At the end of the Self-Test, remove the O-Ring cleaning pad and discard it into a Biohazard waste container. Inspect the vacuum test cup in position B. There must be a small drop of liquid on the middle part of the cup, without spilling to the surrounding area. If there is a spill, self-test is considered failed; troubleshoot and repeat (see section 6.4).
11.	Remove the vacuum test cups from both of the priming cartridges and discard them into a biohazard waste container.
12.	Press "Previous Screen" two times to return to the System Ready display.
13.	When complete, check the instrument print out and review for any failures. If there is a failure, the self-test must be repeated (see section 6.4).

8.3	Testing Procedure
1.	Utilize Platelet Function Test (PFA100) Worksheet for recording patient results.
2.	Take as many COL/EPI test cartridges as needed (2 of each recommended/test) from the pouch and reseal the pouch using the re-closeable seal and return the pouch to the refrigerator. Allow test cartridges to come to room temperature (takes about 15 minutes).
3.	Remove and discard the top foil seal from the test cartridge.
4.	Place the test cartridge in the PFA-100 cassette and push until the test cartridge securely snaps in place. ~~(refer to picture on page 6 in the PFA-100 Operating Manual)~~
5.	**Note:** The following steps must be performed in sequence without interruption.
6.	Mix the specimen by inverting gently by hand 3 – 4 times.
7.	Place the cassette with the test cartridge into incubation well A of the instrument so that the cassette is flush to the carousel surface. Do not apply pressure to the sample reservoir opening.

8.	Pipette 800-1,000 µl (900 µl) of whole blood along the side of the smaller opening on the test cartridge (sample reservoir opening). Dispense slowly to avoid entrapment of bubbles/air in the sample reservoir.
9.	From the System Ready display, press "RUN".
10.	Use the numeric keypad to enter the patient or control ID number.
11.	Press the soft key next to "RUN".
12.	After testing is complete, the instrument will print and display the results along with the test type. Remove the test cartridge by gently pulling the bottom of the cartridge toward you until it releases. Dispose of the test cartridge in the Biohazard waste container.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Interpretation	Collagen EPI result	Collagen ADP result
Normal	Normal	Normal
ASA affect	Prolonged	Normal
VWD or Platelet disorder	Prolonged	Prolonged

This test provides an indication of platelet function. R esults are reported by the instrument as Closure Time (CT). A CT above the established reference range may indicate a slowdown in platelet function and further diagnostics testing might be needed. A CT slightly below the established reference range is not clinically significant; however a CT that is well below the established reference range, will need further diagnostic testing.

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

Seconds

10.4 Clinically Reportable Range (CRR)

31 – 300 seconds

10.5 Repeat Criteria and Resulting

If the result is	Then….
Maximum test time exceeded >300 seconds (A)	Repeat the test using a fresh cartridge; if over 300 seconds upon repeat, report >300.
Test Terminated Due to Air Leak (B)	• Verify that sample and appropriate volume of sample (900 µL) was added to test cartridge. • Prime system from maintenance menu. • Check trigger solution volume and bottle placement • Repeat test. • If the error still remains, do not report the result. Call Siemens technical support and inform Lead/Tech in charge.
Test Terminated Due to Flow Obstruction (C)	• Repeat test with new cartridge. • Check sample for clots or aggregates. • Recollect blood sample and repeat test. • If the error still remains, do not report the result. Call Siemens technical support and inform Lead/Tech in charge.
Test Terminated Due to Insufficient Sample (D)	• Verify sample hematocrit, platelet count, and sed rate history. • Repeat test with new cartridge and 900 µL of sample; results may be reported as the time in which the test ended ">xxx sec" with a statement qualifying the sample properties (i.e. abnormal hematocrit or low platelet count)
Test Terminated Due to Maximum Syringe Travel (E)	• Verify sample hematocrit. If hematocrit is abnormal, the sample may have low viscosity which may induce platelet dysfunction. • Repeat test with new cartridge and 900 µL of sample; results may be reported as the time in which the test ended ">xxx sec" only if the time lies above the reference range. The report should include a statement qualifying the sample properties (i.e. abnormal hematocrit or platelet count)

11. EXPECTED VALUES

11.1 Reference Ranges

Collagen/Epinephrine	94 - 193 seconds
Collagen/ADP	71 - 118 seconds

11.2 Critical Values

None

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS:

Platelet function results should be evaluated in conjunction with clinical history, clinical presentation, and other laboratory findings. Prolonged closure times maybe seen with low hematocrit as well as thrombocytopenia.

Interpretation	Collagen EPI result	Collagen ADP result
Normal	Normal	Normal
ASA affect	Prolonged	Normal
VWD or Platelet disorder	Prolonged	Prolonged

12. CLINICAL SIGNIFICANCE

The PFA-100 test provides an indication of platelet function. Closure Times above the laboratory cut-off may indicate the need for further diagnostic testing. Results should always be evaluated in conjunction with clinical history, clinical presentation, and other laboratory findings (such as bleeding time, CBC, and platelet aggregometry).

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

31 – 300 seconds

14.2 Precision

Refer to the package insert for the precision data and case study information.

14.3 Interfering Substances

- Presence of hemolysis may interfere with test results. The presence of free hemoglobin from lyses of red blood cells could affect the PFA-100 closure time for two reasons: 1) reduction in hematocrit and 2) release of ADP. Therefore, use of hemolyzed blood for PFA-100 testing is not recommended.

- The presence of fatty acids and lipids found in various human diets are widely known to inhibit platelet function. Neutral lipids, such as cholesterol, generally have no effect on platelet function.
- Platelet inhibiting agents, such as Aspirin and anti-glycoprotein IIb/IIIa antagonists, directly affect platelet function.

14.4 Clinical Sensitivity/Specificity/Predictive Values

- Differences in subject population, Aspirin dosage, the time of testing after Aspirin ingestion and the anticoagulant used during blood sample collection will affect the results.
- Micro-thrombi in the sample or particulates introduced into the sample from the environment could adversely affect the test results due to the detection of a flow obstruction.
- Blood samples with high sedimentation properties may experience some settling in position B while waiting to be tested in sequence with position A. 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 single tests.
- Many medications are known to affect platelet function. Therefore, the medication history of the patient should be reviewed. See addendum B for list of the medications.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. N early all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. P lease ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Hemolysis, Icteria and Lipemia Interference (Lab policy)
5. Repeat Testing Requirements (Lab policy)
6. Control Donor Group list
7. Current package insert Siemens Dade PFA-100® Test Cartridges
8. PFA-100® QC and Maintenance form (AG.F117)
9. PFA-100® Establishment of Control Donor Group Data Form (AG.F118)
10. Platelet Function Test (PFA100) Worksheet (AG.F119)
11. PFA100 Lot To Lot Cross Check Log (AG.F120)

17. REFERENCES

1. Siemens PFA-100® Platelet Function Analyzer operating manual 46978, printed 2008.
2. Siemens PFA-100® System Getting Started Guide 46977, printed 2008.
3. Siemens PFA-100® Educational Support Tool 4A100, 2009.
4. Siemens Dade PFA-100® Reagents Package Insert, Edition July 2009.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/18/14	2	Added definitions	Z Morrow	R SanLuis
000	3/18/14	6.1	Change Patient Normal Group to Control Donor Group	Z Morrow	R SanLuis
000	3/18/14	6.3, 6.4	Add Control Donor Group criteria	Z Morrow	R SanLuis
000	3/18/14	6.7	Add reference to cross check log	L Barrett	R SanLuis
000	3/18/14	16	Move forms from section 19, add cross check log	L Barrett	R SanLuis
000	3/18/14	19	Remove forms	L Barrett	R SanLuis
000	3/18/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
1	9/19/14	3.1	Add detail to specimen collection	A Chini	R SanLuis
1	9/19/14	3.2	Add Greiner Bio-One as preferred tube	A Chini	R SanLuis
1	9/19/14	6.4	Add troubleshooting for self-test	A Chini	R SanLuis
1	9/19/14	8.2	Clarified self-test process	A Chini	R SanLuis
2	7/13/16	Header	Add WAH	L Barrett	R SanLuis
2	7/13/16	2	Update wording	A Chini	R SanLuis
2	7/13/16	3.1	Add a statement on venous collapse and or stoppage during blood collection	A Chini	R SanLuis

2	7/13/16	6.1	Add details on control donor group	A Chini	R SanLuis
2	7/13/16	6.3	Clarify QC frequency	A Chini	R SanLuis
2	7/13/16	6.4	Add control group limits	A Chini	R SanLuis
2	7/13/16	6.6	Add control group documentation	A Chini	R SanLuis
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2	7/3/16	8.3	Reword steps 4 and 6	A Chini	R SanLuis
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2	7/13/16	10.5	Add detail to resolve error messages	A Chini	R SanLuis
2	7/3/16	11.3	Add report comment	L Barrett	R SanLuis
2	7/13/16	14.2	Add statement on precision	A Chini	R SanLuis
2	7/13/16	14.4	Update sensitivity	A Chini	R SanLuis
2	7/13/16	19	Add Addendum B	A Chini	R SanLuis

19. ADDENDA

Addendum	Title
A	Maintenance Procedures
B	Medications that Induce Temporary Platelet Dysfunction

Addendum A

Maintenance Procedures

A. It is recommended by Siemens to perform manual O-ring cleaning on a weekly basis and the O-ring should be replaced on a yearly basis. In addition, the manual O-ring cleaning procedure should be performed whenever the status message [VACUUM TEST FAIL] is obtained after a self test or whenever the status message [TEST TERMINATED DUE TO AIR LEAK] is printed after a test.

B. **Remove the 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 (6) to select the Remove O-ring option.
4. 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.
5. 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.
6. 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 5 should be repeated. If the Service Tool fails to remove the O-ring again, contact the Technical Assistance Center.)
7. Invert the O-ring Service Tool and tap against the palm of your hand to remove the O-ring.

C. **Manual O-ring Cleaning Procedure:**
1. Rinse the O-ring under running tap water.
2. Place O-ring between forefinger and thumb and remove any debris by using a rubbing motion while rinsing under tap water.
3. Visually inspect the O-ring for debris or unusual wear and tear, such as cracks. (If the O-ring has unusual wear and tear, replace with a new one.)
4. Shake off excess water and rub the O-ring between forefinger and thumb using an alcohol prep pad.

D. **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 Install O-ring option.
4. The system will display the message Load O-ring Service Tool. Be sure to load the 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 with the carousel surface.
5. 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 removal of the O-ring Service Tool.

6. Remove the O-ring Service Tool.
7. Press the softkey next to Continue.
8. Perform a self test from the Maintenance menu to verify that the system has no vacuum leak.

Addendum B

Medications that Induce Temporary Platelet Dysfunction

Antibiotics
Ampicillin
Chlortetracycline (Areomycin)
Carbenicillin
Nitrofurantoin (Furadantin)
Gentamicin
Cephalothin (Keflin)
Moxalactam
Nafcillin
Piperacillin
Quinacrine

Cardiovascular/Respiratory
Aminophylline
Clofibrate
Phenoxybenzamine (Dibenzyline)
Dicumarol
Dihydroergotamine
Dipyridamone (Persantine)
Heparin
Hydralazine
Isoproterenol (Isuprel)
Nitroglycerin
Nitroprusside
Papaverine
Propranolol
Phentolamine (Regitine)
Reserpine
Theophylline
Verapamil

Miscellaneous Drugs
Alcohol
Aminocaproic acid
Diphenhydramine (Benadryl)
Caffeine
Cyclosporine
Dextran
Glycerol guaiacolate
Hydroxyethyl starch
Hydrocortisone
Methylprednisolone
Cyproheptadine
Promethazine (Phenergan)
Methysergide maleate
Tocopherol
Tranexamic acid
Vinblastine
Vincristine

Anti-Inflammatory Drugs
Sulfinpyrazone
Aspirin
Colchicine
Ibuprofen (Motrin)
Indomethacin
Fenoprofen
Naproxen (Naprosyn)
Phenylbutazone
Mefenamic acid (Ponstel)

Psychiatric Drugs
Nortriptyline (Aventyl)
Amytriptyline (Elavil)
Desipramine (Norpramine)
Doxepin (Sinequan)
Tryfluoroperazine (Stelazine)
Chlorpromazine (Thorazine)
Imipramine (Tofranil)

Anesthetics
Cocaine
Dibucaine (Nupercaine)
Procaine
Lidocaine (Xylocaine)

Diuretics
Acetozolamide
Ethacrynic acid
Furosemide

Antiplatelet Drugs
ReoPro
Integrelin
Aggrastat
Clopidogrel
Ticlid

Advil
Anacin
Anaprox
APC w/codeine
A.S.A.
A.S.A. compound w/codeine
Aspergum
Aspirin-children's
Bayer-children's
Bufferin
Cama inlay
Coricidin
Coricidin Demilets
Darvon w/A.S.A.
Darvon Compound
Dristan
Ecotrin
Empiral
Empirin w/codeine
Emprazil-C
Excedrin
Fiorinal
Fizrin
IBU (Ibuprofen Tablets)
Lortab A.S.A.
Measurin
Meclomen Capsules
Nalfon
Norgesic
PAC compound
Pedia-Profen
Ponstel
Robaxisal-PH
St. Joseph's
Super-Anahist
Synalogs-DC
Toradol Vanquish

Alka-Seltzer
Anahist
APC
APC w/demerol
A.S.A. compound
Ascriptin A/D
Aspirin (USP)
Bayer
Bayer timed release
Calurin
Cope
Coricidin "D"
Coricidin Medilets
Darvon-N w/A.S.A.
Dolene Compound
Easprin
Ecotrin
Empirin
Emprazil
Equagesic
Excedrin PM
Fiorinal w/codeine
4-way cold tablets
Liquiprin
Lodine Capsules
Midol
Motrin
Naprosyn
Nuprin
PAC compound w/codeine
Percodan
Relafen
Sine-Off
St. Joseph's for children
Synalogs
Triaminicin

List of the medications which contain aspirin:

Ibuprofin
The ibuprofen medications (such as Advil, Nuprin, Motrin, etc.) also cause a tendency towards bleeding. For this reason, avoid all ibuprofen medications beginning 2 days before testing.

Prescription

Aggrenox
Ascriptin with Codeine Tablets
A.S.A. and Codeine Compound
Axotal Tablets
Bufferin with Codeine #3 Tablets
Darvon with A.S.A. Pulvules
Darvon Compound-65
Disalcid Capsules
Easprin
Empirin with Codeine Tablets
Equagesic Tablets
Fiorinal Tablets
Fiorinal with Codeine
Magan Tablets
Micrainin Tablets
Norgesic & Norgesic Forte Tablets
Pabalate-SF Tablets
Percodan & Percodan-Demi Tablets
Robaxisal Tablets
Synalgos-DC Capsules
Trilisate Tablets & Liquid
Talwin Compound
Zorprin Tablets

Non-Prescription

Alka-Seltzer Effervescent Tablets
Alka-Seltzer Plus Cold Medicine
Anacin Tabs & Caps., Max strength
Arthritis Str. Bufferin Tablet
A.S.A. Tablets
Ascriptin Tablets
Ascriptin A/D Tablets
Aspergum
Aspirin Tablets 5 grain
BC Tablets and Powder
Buffering Tablets
Cama Arthritis Pain Reliever
Congesprin Chewable Tablets
Cope Tablets
Coricidin "D" Decongestant Tablets
Coricidin Tablets
Doan's Pills
Ecotrin Tablets
Empirim Tablets
Excedrin Tablets & Capsules
4-Way Cold Tablets
Measurin Tablets
Midol Caplets

Quest Diagnostics™

PFA100 LOT TO LOT CROSS CHECK LOG

☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

Collagen	Lot Information	Date Rec'd	QC Donor	Test Results		Average of Results	TEA (≤ 25%)	Tech	Test Date
EPI	**Current Lot #:** **Current Lot Exp:**			**First Run:**	**Second Run:**				
EPI	**New Lot #:** **New Lot Exp:**			**First Run:**	**Second Run:**				
ADP	**Current Lot #:** **Current Lot Exp:**			**First Run:**	**Second Run:**				
ADP	**New Lot #:** **New Lot Exp:**			**First Run:**	**Second Run:**				

TEA Calculation: $1 - \left(\frac{\text{Average of the smaller value}}{\text{Average of the larger value}}\right) = \_\_\_\_\_ \times 100 = \text{TEA}$

Space for calculations:

Interpretation:
TEA value of ≤ 25 is acceptable for patient testing. TEA value greater than 25% requires Medical Laboratory Director Approval prior to use for patient testing.

☐ **New Lot Acceptable for patient testing** ☐ **New Lot Rejected for patient testing** ☐ **New Lot Approved by Medical Director: _____**

Comments: _____

_____

Group Lead Signature: _____ **Date Reviewed: _____**

Supervisor Signature: _____ **Date Reviewed: _____**

Quest Diagnostics™

☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

PFA-100® Control Donor Group Data Form

Specification: The control donor results must be within the acceptable range.

Collagen/Epinephrine Acceptable Range: 106 – 181 Seconds
Collagen/ADP Acceptable Range: 77 – 112 Seconds

Date	Tech	Donor ID	Collagen/ADP Result	Collagen/EPI Result	Accepted Donor Rejected Donor	Comments (Reason for testing or reason for donor exclusion)
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	
					☐ Accepted ☐ Rejected	

Reviewed By:	Date:	Reviewed By:	Date:	Reviewed By:	Date:
Reviewed By:	Date:	Reviewed By:	Date:	Reviewed By:	Date:
Reviewed By:	Date:	Reviewed By:	Date:	Reviewed By:	Date:
Reviewed By:	Date:	Reviewed By:	Date:	Reviewed By:	Date: