TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	10/8/2014
Department:	Core	**Due Date:**	10/21/2014
		Implementation:	**10/22/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Platelet Function - PFA-100 SGAH.G06,WAH.G07 v2

PFA100 Lot To Lot Cross Check Log AG.F120.3

Description of change(s):

SOP:

Section	Reason
3.1	Add detail to specimen collection
3.2	Add Greiner Bio-One as preferred tube
6.4	Add troubleshooting for self-test
8.2	Clarified self-test process

FORM:
Correct formula for calculating CV, change ‘old lot’ to ‘current lot’

This revised SOP and log will be implemented on October 22, 2014

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

Approved draft for training at all sites

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

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 agonists. 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.

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 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.

Definitions

Control Donor Group - A group of qualified QC donors that have a Closure Time near the middle of the normal range and replicate results within acceptable coefficient of variation limits.

Coefficient of Variation (CV) - Ratio of the standard deviation. The value is used to determine the instrument’s precision.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None

Component	Special Notations
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. • 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 **-Other Acceptable**	Whole Blood None
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.

Form revised 2/02/2007

Criteria	
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 Material Safety Data Sheet (MSDS) 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	Quantity
PFA-100® Collagen/EPI Test Cartridge	Siemens - Cat # B4170-20A	20/Box
PFA-100® Collagen/ADP Test Cartridge	Siemens - Cat # B4170-21A	20/Box
PFA-100® Trigger Solution	Siemens - Cat # B4170-50	3 – 5 ml bottles
Isopropanol 70%	Fisher Scientific A459-1	1 Bottle

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 Material Safety Data Sheet (MSDS) 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
  A Control Donor Group is identified and maintained. These individuals will not have von Willebrand disease, any platelet dysfunction disease, and are free of any medication containing acetyl salicylic acid (ASA).

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.
- An acceptable donor from the Control Donor Group will be analyzed with each new shipment of test cartridges, new lot numbers of test cartridges, and after a major repair on the PFA-100.

6.4 Tolerance Limits

The PFA-100® "Self Test" must pass all internal parameter checks and external inspection criteria (refer to section 8.2, steps 10 - 13).
The previously tested normal patient must return values within the normal range for both COL/EPI and COL/ADP tests.

The control donor must be run in duplicate and return results within the normal range.

Analyte	Normal Range	Mean	Acceptable CV
Collagen/Epinephrine	94 - 193	144	12.7 %
Collagen/ADP	71 - 118	95	12.4 %

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.
Third Time	If problem persists, contact technical assistance center

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results. Computer aided tools should be used when available.

6.6 Documentation

Document QC results on the PFA-100 QC/Maintenance log.

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. 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.

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 uL 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 Daily Self-Test.
2.	Check Trigger solution for volume 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
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(s) 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 patient or control 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

10.2 Rounding

None

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.
Test Terminated Due to Flow Obstruction (C)	• Repeat test with new cartridge • Check sample for clots or aggregates. • Recollect blood sample and repeat test.
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 platelet count)
Test Terminated Due to Maximum Syringe Travel (E)	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 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 Priority 3 Limit(s)

Call results when the CRR is exceeded.

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

Normal Patient Mean
EPI CV <12.4%
ADP CV <12.7%

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

The manufacturer's published PFA-100 System vs. Platelet Function Status (PFS) Comparison:

	PFS Normal [n]	PFS Abnormal [n]
COL/EPI PFA Normal	156	6
COL/EPI PFA Abnormal	20	146

Overall clinical sensitivity and specificity were calculated from the table above at 96.1% and 88.6% respectively. Also, results by clinical sites were computed and from 86.7% to 100.00% for clinical sensitivity and from 79.3% to 100.0% for clinical specificity. The data presented above reflect the clinical performance of the PFA-100 System with COL/EPI test cartridges at cut-off of 170 seconds. (Siemens, Dade PFA-100 Package Insert, July 2009)

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly 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. Please 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. Material Safety Data Sheets (MSDS)
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

19. ADDENDA

Addendum	Title
A	Maintenance Procedures

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.

Quest Diagnostics

☐ Germantown Emergency Center
☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

PFA100 LOT TO LOT CROSS CHECK LOG

Indicate which reagent: ☐ **Collagen (EPI)** or ☐ **Collagen (ADP)**

New Lot #	**Date Rec'd**	**Exp. Date**	**Normal QC Donor's name**	**Normal QC Results** (run in triplicate)	**Test Date**	**Tech**
				1.		
				2.		
				3.		
				Average:		
Current Lot #	**Date Rec'd**	**Exp. Date**	**Normal QC Donor's name**	**Normal QC Results** (run in triplicate)		
				1.		
				2.		
				3.		
				Average:		

RESULTS: **CV** = 1 - $\left[\frac{\text{Average of the New Lot}}{\text{Average of the Current Lot}}\right]$ x 100 **CV** = _____**%**

Circle one: **A** = **A**cceptable (CV ≤ 12%)
U = **U**nacceptable (CV > 12%)

Corrective Action if Unacceptable: _____

_____

_____

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

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