Strong Memorial Hospital
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PFA-100 Procedure (adapted from SH.CP.AU.coa.0032)

1. Allow the test cartridge(s) to reach room temperature prior to utilization (approximately 15 minutes). Peel off and discard the top foil seal of the test cartridge.

2. Snap the test cartridge into position “A” of the PFA-100® cassette. When running two tests, place a second test cartridge into position “B”. Do not apply pressure to the sample reservoir opening. Two different types of test cartridges may be placed in the cassette (eg. Collagen/EPI and Collagen/ADP). The analyzer will automatically detect the test cartridge type before testing the sample.

Note: The following steps must be performed in sequence without interruption.

3. Check the sample for a clot using two applicator sticks. Resuspend the whole blood sample by gently inverting the collection tube 3-4 times by hand.

4. Pipette 800µL of sample into the smaller opening (sample reservoir opening) of the test cartridge by dispensing slowly along one of the inside corners. The test can now be started.

5. Press the softkey located next to [RUN] on the System Ready display.

6. Use the numeric keypad to enter the numeric patient ID.

7. The instrument will start testing without action from the operator. When testing is complete, the system will print and display the results.

8. Remove the cassette carefully from the carousel. Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps. Dispose of the test cartridge in a suitable biohazard waste container.

REPORTING RESULTS

A numeric result **without an error flag** can be reported.

If the "CT/EPI" result is within the **normal range (0–181)**, report and verify the result.

If the "CT/EPI" result is **above** the normal range (**>181)**, report and verify "CT/EPI" and the CT/ADP test will reflex.

If the CT ADP result has no error flag, report and verify.

PFA ERROR CODES

Closure time results which are flagged with a **FLOW OBSTRUCTION, INSUFFICIENT SAMPLE**, **MAXIMUM SYRINGE TRAVEL REACHED** or **>300A SEC MAX TEST TIME EXCEEDED** code can be the result of several sample problems including insufficient sample volume, air bubbles, partial clots, platelet clumping and/or giant platelets, low hematocrit or low platelet count.

When **any** of these codes are encountered, the following steps should be taken to rule out sources of the error:

1) Recheck the sample for a clot and have a slide made for review.
2) If there is evidence of platelet clumping or fibrin strands, .ND the test and use the canned text @SPIM - UNABLE TO MEASURE DUE TO PLATELET CLUMPING INTERFERENCE.
3) If there is evidence of giant platelets, .ND the test and use the canned text @GPP - UNABLE TO MEASURE DUE TO GIANT PLATELETS
4) If there is no evidence of interference on the slide, then perform a self-test on the PFA analyzer.
5) If the self-test fails, troubleshoot the analyzer. If the self-test passes, follow instructions below regarding specific error code on original run.

INSUFFICIENT SAMPLE / MAXIMUM SYRINGE TRAVEL REACHED

1) In the case of insufficient sample error or maximum syringe travel reached, check the patient's hematocrit and platelet count. If the hematocrit is < 35% and/or the platelet count is <150,000, run the test with 900 µL of sample.
2) If the platelet and/ or the hematocrit is below the threshold and a valid result occurs with 900 µL of sample, report the result with the canned message "Interpret results with caution – platelet counts <150 and hematocrits <35% can adversely affect closure time results."
3) If the platelet and hematocrit are above each parameter or levels are unknown, rerun the sample with 900µL. If a valid result occurs, report the result.
4) If the error codes still persist, .ND the test and use the canned text @SDNA - DATA ANALYTICALLY UNACCEPTABLE.

FLOW OBSTRUCTION

1) In the case of flow obstruction with no visible clot, giant platelets, platelet clumps or fibrin strands, rerun the sample with 800 µL.
2) If a valid result occurs with no error on the rerun, the result can be verified.
3) If the error codes still persist, .ND the test and use the canned text @SDNA - DATA ANALYTICALLY UNACCEPTABLE.

>300A SEC MAX TEST TIME EXCEEDED

This error could be caused by any of the sample problems above or it could be a true value.

1) If there is only enough sample to run the patient only one more time, run the patient with the CT/ADP cartridge.
2) If there no other error codes and there is enough sample to rerun the patient at least two more times, rerun the CT/Epi cartridge with 800 µL of sample. If the “>300A” code reoccurs, report the CT/Epi as “>300”, and run the COL/ADP cartridge.
3) If there are no other error codes associated with the reruns, report both CT/Epi and CT/ADP results.

NOTE: Any steps taken in troubleshooting should be documented as internal comment(s) on the order next to the test result and on the Manual Coag test log.