This procedure applies to:
- Stanford Hospital & Clinics Decentralized Testing

**PURPOSE**

The i-STAT Kaolin Activated Clotting Time test, (ACT), is a measure of the time required for whole blood to clot after activation of the intrinsic coagulation pathway. It is a point-of-care test used to monitor heparin therapy during cardiopulmonary bypass surgery and other vascular procedures in the Stanford Operating Room.

**EQUIPMENT AND SUPPLIES NEEDED TO PERFORM TESTING**

iSTAT 1 Analyzer with 9 volt rechargeable lithium battery

Note: The iSTAT analyzer should be ready to use unless:

- **The battery is dead.** DO NOT DISCARD the dead battery. Switch it with the battery in the iSTAT docking station in the Anesthesia Work Room (this will recharge it).

- **Internal electronic simulation fails.** An internal electronic simulation of the testing procedure initiates when a cartridge is inserted. It also runs automatically every eight hours. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays the message, “ELECTRONIC SIMULATOR FAIL”. Remove and re-insert the same cartridge immediately after the FAIL message; this will activate the simulator test again. If it fails again, the analyzer may not be used. Call the POCT department at 4-8934 for troubleshooting advice.

- **External electronic simulation is required.** An external electronic simulation of the testing procedure is required periodically; if needed, the analyzer will display the message, “SIMULATOR RUN REQUIRED. An External Electronic Simulator is stored in the Anesthesia Work Room. The EQC is stored at room temperature and the metallic contact pads are protected from contamination by storing in its protective case. External Electronic simulator is used when the I-STAT instrument prompts. Insert the simulator in place of a cartridge and proceed with patient testing when test “PASSED” message is displayed. If “FAIL” message is displayed, gently clean the sensors with an alcohol wipe and re-insert the simulator one more time. If it fails again, the analyzer may not be used. Call the POCT department at 4-8934 for troubleshooting advice. Always return the Electronic Stimulator to the Anesthesia Work Room for storage.
**iSTAT ACT Cartridges**

Note: Cartridges are stored in a refrigerator (2°C to 8°C) in the Anesthesia Work Room. Remove only the minimum number that you expect to use and record the date and your initials on each. Allow them to equilibrate to room temperature for at least 5 minutes before using. Do not remove the cartridge from its sealed pouch until ready to use.

Cartridges should be ready to use unless:

- They are expired because the current date is past the manufacturer’s expiration date on the box.
- They are expired because they were previously removed and allowed to come to room temperature but not used and the current date is more than 14 days after the date initialed on the pouch.

**PRINCIPLE BEHIND TESTING**

A whole blood sample is added to a cartridge containing a particulate activator (kaolin clay particles) and a synthetic substrate of thrombin. The kaolin activates the intrinsic coagulation pathway which activates thrombin. Activated thrombin converts the synthetic thrombin substrate to an electrochemically active product, which is measured by the analyzer.

During cardiopulmonary bypass surgery, patients are heparinized so that the contact surfaces in the extracorporeal line will not activate the coagulation system.

Point-of-care ACT testing is sensitive to the presence of heparin and may aid in the monitoring of heparinization. It is primarily helpful when large doses of unfractionated heparin are used (with concentrations between 1 - 6 units/ml). It is not as helpful during vascular surgery employing lower doses (concentrations between 0.2 - 1 units/ml) or when using low-molecular-weight heparin.

No point-of-care ACT test has been shown to correlate precisely with heparin levels and significant variability may exist between one patient and another based on platelet count and function, patient’s temperature, degree of hemodilution, and other factors.

**HOW TO COLLECT THE SPECIMEN**

Flush the extracorporeal line and discard the first 5ml of blood. Then collect 0.5 cc of fresh whole blood using a plastic syringe without any anticoagulant. Mix gently without creating any bubbles. The sample should be immediately dispensed into the iSTAT ACT cartridge.
PROCEDURE FOR ANALYSIS

1. Universal precautions are observed for all blood specimens. Wash hands and wear gloves when using the I-STAT instrument.

2. Remove the cartridge from its pouch. Do not touch the two contact sensors or squeeze the center. Handle the cartridge only by its edges.

3. Mix specimen gently without creating bubbles, dispel any air from the syringe, and discard the first drop of blood from the specimen onto a gauze pad.

4. Direct the dispensing tip of the syringe containing the blood into the sample well and slowly dispense the sample until it reaches the fill mark on the cartridge.

5. Close the cover over the sample well until it snaps into place. Be careful not to squeeze the center of the cartridge. Pick the cartridge up by the sides.

6. Insert the cartridge into the cartridge door slowly until it clicks into place.

7. Scan your 5-digit operator ID number using the bar code you received during training. (Keep it on your ID badge.)

8. Scan the patient’s MRN # from the wristband. If this is not feasible, manually enter it. (You will need to do this twice.)

9. The analyzer will automatically complete the testing. Do not remove cartridge or disturb the analyzer while test cycle is in process. Press “→” on the iSTAT analyzer key pad to view results in progress.

10. If a result is flagged with “<” or “>”, the result may be outside the cartridge’s measuring range. If a result is flagged with “***”, the cartridge sensor may have been compromised. In either case, repeat test with new cartridge. Results that appear to be inconsistent with patient treatment should be viewed as questionable and the test should be immediately repeated.

11. Do not remove the cartridge while test cycle is in progress. If you wish to check on the status of the testing, press “→” on the iSTAT to view status. It is important that the meter is not disturbed or moved while testing is in progress. Movement generates “test errors” which will necessitate repeat testing with a new sample.

12. When the surgical procedure is over, the iSTAT analyzer should be cleaned with Sani-Cloth wipes before use with another patient. Allow to dry for one minute, then wipe with tissue, gauze or paper towel. Take care not to scratch or mark the surface and avoid getting moisture in the test port area.
13. To insure that the ACT results are entered into the patient’s electronic medical record, insert the iSTAT analyzer into the docking station in the Anesthesia Work Room. It will automatically upload results to EPIC

INTERPRETING RESULTS

The target range for heparinization during cardio-pulmonary bypass surgery is generally cited as 480 seconds. The iSTAT ACT procedure has an analytically measurable and reportable range of 50 – 1000 seconds.

We validated iSTAT ACT test vs. the Hemochron Jr. analyzer previously used in the Stanford Operating Room. The reference range (baseline) of 70-140 seconds was comparable. Heparinized patients, however, showed a bias with iSTAT ACT results, on average, 60 seconds longer than Hemochron Jr. results. iSTAT ACT results >200 seconds correlate with heparin levels >1 U/ml; >400 seconds with levels >2 U/ml and >600 seconds with levels >3 U/ml.

Many other individual patient factors may influence ACT testing and make the guidelines listed above unreliable. An unanticipated ACT result should always be followed up with additional studies to define the cause of the abnormal result.

REFERENCES

- Abbott Point of Care iSTAT ACT Cartridge and Test Information sheet
- Abbott Point of Care iSTAT User Guide

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