A. Purpose:
   The i-STAT Kaolin Activated Clotting Time test is a measure of the time for complete
   activation of the coagulation cascade. The i-STAT ACT test is similar to traditional ACT
   test except that the endpoint is indicated by the conversion of a thrombin substrate other
   than fibrinogen and an electrochemical sensor is used to indicate the conversion. The
   substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-
   cleaved amide linkage in fibrinogen.
   The i-STAT ACT test is calibrated to match the Hemochron Celite FTCA510 using
   prewarmed reagent tubes.

B. Intended Use:
   The i-STAT Kaolin Activated Clotting time test is an in vitro diagnostic test that uses
   fresh whole blood to monitor high-dose heparin anticoagulation frequently associated
   with cardiovascular surgery. The test is to be used with the i-STAT Portable Clinical
   Analyzer.
   1. Contents
      Each i-STAT System test for Kaolin Activated Clotting Time (ACT) measures
      the time interval required to complete activation, by kaolin, of the coagulation
      cascade in arterial or venous whole blood (dimension seconds) for in vitro
      monitoring of high-level heparin therapy. Presently, no international
      conventional reference measurement procedure or international conventional
      calibrator for Kaolin ACT is available. Kaolin ACT values assigned to i-STAT
      controls are traceable to i-STAT selected reference measurement procedure,
      which employs celite activated glass reagent tubes, an automated timer and
      traditional viscometric clot detection and is run under specified temperature and
      sample conditions. I-STAT System controls are validated for use only with the i-
      STAT System and assigned values may not be commutable with other methods.
   2. Expected Values
      Test/Abbreviation Units Manufacturer's Reference Range Reportable Range (PREWARM)
      Activated Clotting seconds  50-1000  74-137
   3. Clinical Significance
      The ACT is primarily used to monitor a patient’s state of anticoagulation from
      heparin that is administered during a medical or surgical procedure. It is
commonly employed in cardiac catheterization, percutaneous transluminal coronary angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

C. Policy:
1. A physician/PA's order is required or is part of a Nursing Protocol for this specific Nursing unit.
2. Test will be performed by employees certified by the Pathology POCT coordinator using correct policy and procedures designated for LifeBridge Health.
3. Patient and Operator ID must be entered into the instrument each time a test is performed.
4. Patient results will be transmitted to Cerner where they can be viewed in Powerchart.
5. Monthly reports will be distributed to Nursing Directors of units performing tests identifying problems found. Follow-up and corrective action should be returned to Point-of-Care Leader/Technical Specialist where these reports will be filed.
6. Certifications will include an in-service, performing a test, and taking a written test.
7. Re-certification is performed after 6 months during the first year of employment and then yearly.
8. Only LifeBridge Health employees will perform tests.
9. Documentation of certification is maintained in the employee's personal file, and Pathology.

D. Specimen:
1. Test can be performed using venous or arterial samples
2. Collection
   a. Good blood flow must be used.
   b. Samples for testing should be drawn in plastic collection devices (plastic syringe).
   c. The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate. Blood gas syringes are NOT acceptable.
   d. Collection device cannot contain clot activators or serum separators.
   e. The sample should be immediately dispensed into the sample well of the cartridge.
   f. If a second measurement is required, a fresh sample must be obtained.
   NOTE: Some experts recommend drawing and discarding a sample of at least 1.0 mL prior to drawing sample for coagulation testing.
3. In-dwelling line
   a. Fluid drip through the line must be discontinued.
   b. If blood must be drawn from indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.
   c. Withdraw the sample for testing into a fresh plastic syringe.
   d. The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate. Blood gas syringes are NOT acceptable.
   e. The sample should be immediately dispensed into the sample well of a cartridge.
f. If a second measurement is needed, draw a fresh sample.

4. Extracorporeal line
   a. Flush the extracorporeal blood access line by withdrawing ~5.0 ml. of blood into a syringe and discard the syringe.
   b. Withdraw the sample for testing into a fresh plastic syringe.
   c. The collection syringe cannot contain anticoagulants such as heparin, EDTA, oxalate, or citrate. Blood gas syringes are NOT acceptable.
   d. The sample should be immediately dispensed into the sample well of a cartridge.
   e. If a second measurement is needed, draw a fresh sample.

E. Test Limitations
   The i-STAT Kaolin ACT is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass prematurely activates coagulation resulting in accelerated clotting times.
   The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be inaccurate by more than 10%. Hemodilution may affect results.
   Platelet dysfunction, factor deficiencies, dysprothrombinemia, pharmacological compounds, and other coagulopathies may affect the results of this test.

F. Storage
   Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 to 30°C). Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes, equilibration. A cartridge should be used immediately after it is removed from the pouch.

G. Quality Control
   On each day the analyzer are in use, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.
   On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. Two levels of controls in duplicate will be run from each shipment/lot number of cartridges. Two levels of controls will be run weekly by operators on units for each lot number that is used on units.

For use of instrument, downloading, transmitting results, see procedure for i-STAT One.

References
