Quality Control

- PT/INR---2 levels of liquid QC to be tested monthly After initial validation (20 days of liquid QC in parallel with electronic QC)
- ACT-Celite—2 levels of liquid QC to be tested monthly After initial validation (20 days of liquid QC in parallel with electronic QC)

Intended Use PT/INR

- i-STAT PT/INR cartridges are ONLY intended for monitoring patients receiving oral anticoagulation therapy such as Coumadin or warfarin.

Sample Type i-STAT PT/INR

- FIRST drop of blood from capillary or venous whole blood tested IMMEDIATELY after collection
- Do NOT collect sample from a line or catheter
- Capillary samples
  - Test the **FIRST drop of blood**.
    - This is different than the glucose meter sample collection/testing process.
  - I-STAT recommends filling cartridge directly from skin puncture.
    - Capillary tubes are NOT recommended for PT/INR testing.
- Venous Whole blood
  - Collect in a Plain Plastic syringe without anti-coagulant
  - Fill cartridge without needle and Prior to filling any other blood collection tubes
  - Use first drop of blood from syringe
  - Transfer devices should Not be used to transfer sample to the cartridge
  - Metal needles should Not be used when filling an i-STAT cartridge
  - If sample testing is delayed, results will be adversely affected

i-STAT PT/INR Notes

- If an error code 19 occurs (no clot detected), draw a venous sample and send to the Core Lab.
- Any INR > or = 4.0 should have a follow-up (confirmatory) venous sample sent to the Core Lab.
  - Must use comment code 123 – "*laboratory confirmation to follow*" to avoid duplicate billing
- i-STAT PT/INR may report a falsely prolonged prothrombin time (PT) and an elevation of the INR on samples contaminated with Chlorhexidine Gluconate. This chemical can be found in some skin cleansing solutions.

Intended Use i-STAT ACT-Celite

- i-STAT Celite Activated Clotting Time (CeliteACT) test is an in vitro diagnostic test that uses fresh, whole blood, and is useful for monitoring patients receiving heparin for treatment of pulmonary embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures such as catheterization, cardiac surgery, surgery, organ transplant, and dialysis.

Sample Type i-STAT ACT-Celite

- ONLY whole blood should be tested.
- NEVER use a capillary sample for ACT testing!
- NEVER use a pre-heparinized or anti-coagulated collection container for ACT testing
- Plastic collection containers must be used
- Squirt out the first drop of blood from syringe, prior to filling test cartridge
- Test IMMEDIATELY after collection -- Do NOT let the sample sit for any period of time prior to testing
- If collecting an ACT from a line, Always adequately 'clear' line prior to collecting a sample for testing on i-STAT.
- Inaccurate results will be given if a sample is contaminated.
- Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample.
    - If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered.
    - The line should be flushed with 5mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.
    - Accurate results depend on an adequate back flush to eliminate the possibility of sample contamination with IV fluids.
    - Caution should be taken when collecting from lines which have had fluids that could adhere to the sides of the tubing. These lines may be difficult to adequately 'clear'.

i-STAT ACT-Celite Methodology Notes

- Different than Hemochron Response tube technology.
    - Does not use mechanical detection of clot
    - The endpoint is indicated by the conversion of a thrombin substrate
    - An electrochemical sensor is used to detect this conversion
    - **Do NOT report ACT results until the final endpoint value is displayed.**
        - If ACT values are prematurely interpreted, inappropriate patient treatment could occur.

PT/INR and ACT-Celite Result Considerations

- Do NOT use a metal needle to fill cartridge
- Do NOT move/carry the analyzer during sample testing
- Do NOT vibrate the analyzer
- Do NOT tilt the analyzer during testing. The analyzer MUST remain flat during sample testing
- Refer to the i-STAT System Manual—Cartridge Test Information (CTI) sheets for other factors which can adversely affect results
  - Certain medications can interfere with i-STAT ACT and PT/INR methodology
- Samples diluted with IV fluids will give inaccurate results
- Results should be carefully evaluated
- Contamination may be indicated by:
  - Falsely prolonged ACT results
  - Increased PT/INR results
- Unexpected and unexplained results should be repeated by another test method.
- Problems should be reported to the Clinical Laboratory Quality and Point of Care Testing Office

Cartridges:

- A very small inventory of cartridges will be kept in the Cath Lab refrigerator.
- Temperature monitoring and immediate response to temp alarms and failures is a requirement to avoid costly loss of product.
- There must be after-hours coverage to respond to temp alarms.
- Cartridges have a much shorter expiration date than Hemochron tubes.
- Cartridges expire 14 days after being removed from the refrigerator.
  - This is different than the EG7 cartridges.
- NEVER re-refrigerate any i-STAT cartridges.
- There are multiple i-STAT ACT cartridge types. Results are not interchangeable.
  - **Cath Lab uses the ACT CELITE cartridges—green packaging**

Analyzers:

- Cath Lab has purchased 3 additional analyzers --for a total of 5 for Cath Lab.

Downloaders/Rechargers:

- 3 additional downloader/rechargers have been purchased for the Cath Lab
- Analyzers need to stay on the downloader/recharger when not being used.