i-STAT ACT Test Clinical Verification Protocol

The Measurement and Use of a New, Novel, Highly Heparin Sensitive and Specific Activated Clotting Time test (i-STAT ACT) in Patients Undergoing Extracorporeal Circulation and/or Other Cardiac Intervention with High Dose Heparin Anticoagulation
**INTRODUCTION**

During interventional surgical procedures and therapies, such as cardiopulmonary bypass (CPB) and percutaneous transluminal coronary angioplasty (PTCA), the patient’s blood is exposed to many foreign surfaces. These non-biological surfaces are known to exhibit a strong procoagulant effect on the circulating blood. To offset these biological procoagulant circumstances, anticoagulants are routinely administered. These anticoagulants primarily consist in the form of unfractionated heparin. Heparin is usually administered in high concentrations during periods of interventional procedures. During these procedures, the Activated Clotting Time (ACT) and other endpoint based coagulation assays are frequently used to monitor these high levels of heparin and the subsequent effect on patient hemostasis.

**THE i-STAT ADVANCEMENT**

In traditional clot-based tests, an endpoint is indicated when clots eventually form following the cessation of the heparin/ATIII complexes ability to inhibit thrombin. That newly appearing thrombin converts circulating fibrinogen to fibrin and eventually a stabilized fibrin clot mass will be formed. These stabilized clot masses are detected mechanically by the physical displacement of a magnet or other physical objects (flags, iron shavings, etc.) or occlusion of an aperture of chamber.

In the i-STAT ACT test, the endpoint is indicated electrochemically and employ either Celite® or kaolin as the particulate activator. This is achieved by the incorporation of a thrombin-specific substrate (other than the native patient fibrinogen) into the testing chamber. The added synthetic substrate has an amide linkage similar to the thrombin-cleaved amide linkage in human fibrinogen. Therefore, when heparin anticoagulation (antithrombotic capacity) ceases, thrombin reappears in the specimen. This thrombin cleaves both (native patient) fibrinogen and the synthetic substrate preloaded into the cartridge. This cleaving of the synthetic substrate by thrombin releases an electroactive marker molecule into the sample. The increasing concentration of this marker molecule is detected amperometrically by the instrument. The time to generation of the electroactive marker indicates the time in which the functional heparinization no longer provides an antithrombic effect on the test sample.

The advanced chemistry of the i-STAT ACT measures this appearance of thrombin directly and specifically rather than a subsequent secondary (or tertiary) effect of the reappearance of thrombin in the sample (by using stabilized blood clot detection to displace a physical object). The i-STAT ACT test reports the Activated Clotting Time (ACT) as a whole blood time clotting time in seconds.

By using a biochemical means of identifying the clinical endpoint of anticoagulation/antithrombin capacity (signified by thrombin formation), the i-STAT ACT thus maximizes test heparin sensitivity and specificity and minimizing the surgical effects on ACT testing not related to functional heparin (such as dilution, cellular count levels, patient temperature, fibrinogen levels, etc.).

Additionally, by using the advanced i-STAT1 instrumentation, it is also possible to select two distinct result algorithms (PREWRM and NONWRM). Since its inception, numerous changes have taken place to Activated Clotting Time tests, including increased automation and decreased sample volume. Today, there are many new fully automated, low blood volume ACT tests on the market, in addition to the older, macro blood volume, semi-automated tube based systems (i.e., Hemochron®, Actalyke™). The newer, micro sample ACT systems typically employ test cartridges or cards (instead of tubes), and all have incorporated an automatic test cycle prewarm that brings the ACT testing chamber to 37°C prior to measuring the clotting reaction. As blood clotting is an enzymatic reaction, the temperature at which the clotting cycle takes place has a marked impact on the rate at which the blood clot can form. The ACT tests that incorporate a prewarm phase into their method allow the entire clotting reaction to take place at 37°C. ACT tests that do not use a prewarm cycle require a period of time to pass before the blood specimen has reached (and stabilized at) 37°C degrees; the actual time needed to reach 37°C is dependant on the ambient (starting room) temperature of the test tube. For example, a 30°C blood sample placed into a (non-prewarmed) 32°C ACT tube MAY take a few minutes before the reaction (blood, reagent, tube, instrument well) all stabilize at 37°C.
Currently, the i-STAT ACT is calibrated by mathematically adjusting the raw “clot time” (extracted from the rise in current) to match the Hemochron® ACT test tube. This calibration is done in-house periodically by testing cartridges and Hemochron Celite tubes side by side, using a range of heparinized, non-hemodiluted whole blood samples, and using Hemochron tubes prewarmed to 37°C.

Customers who are familiar with macro-sample ACT methods like Hemochron and Actalyke™, and who do not preheat their tubes prior to each test have found that the bias in results between their old method and the i-STAT ACT may require changing familiar clotting time targets. In order to ease the changeover to the i-STAT ACT method under these circumstances, we are now providing a “choice” between the current 37°C calibration and a new “non-prewarm” (ambient temperature) calibration. This additional calibration allows the i-STAT ACT cartridge to deliver results that will be a closer match for those users who are familiar with macro-sample methods without automatic prewarming cycles and should reduce the need to make large changes to ACT target times or ranges. Micro-sample methods (Medtronic HR-ACT, Hemochron Jr. ACT+) already require preheating of the test cuvettes; users familiar with these methods should be comfortable with the current i-STAT 37°C calibration.
OBJECTIVES

The aim of this study is to determine the clinical utility and therapeutic relationship of the i-STAT ACT and a mechanical endpoint based ACT system. The i-STAT ACT is a novel, low blood volume, biochemical endpoint detection system for increased heparin sensitivity and specificity in monitoring heparin anticoagulation in patients undergoing extracorporeal circulation (CPB) where multiple environmental factors (sternotomy, hemodilution, hypothermia) have traditionally influenced ACT measurement therefore decreasing heparin specificity and ACT utility. In addition, this study protocol can additionally be used for patients undergoing high dose heparin anticoagulation during interventional procedures (e.g. angioplasty). For CABG or other surgical procedures that use aprotinin (Trasylol™), it is recommended to use kaolin or non-Celite activators for the ACT test.

PRE-STUDY EXPECTATIONS/SURVEY

1. Gather information from discussions held with all appropriate individuals (end users/POCC)
2. Determine if ACT need is Celite or kaolin or both (examine existing practices for information)
3. Identify the departments involved in the performance verification (hint: the goal is to collect samples that will cover the linear range for BOTH ACT instruments [typically 80-800 secs.] as much as possible).

CVOR/Cath Lab/Interventional Radiology:
   a. Ask how many tests do they run per case?
   b. What is the time interval between testing?
   c. How many cases per day?
   d. What type(s) of activators are used?
   e. Do they perform any beating heart (off pump) surgeries (CVOR only)
   f. Record any relevant concomitant therapies (aspirin, antiplatelet therapy, aprotinin, etc.)

ICU’s and Dialysis:
   1. How many tests per day?
   2. What type(s) of activators are used?
   3. Record any relevant concomitant therapies (erythropoetin (Epogen®/ProCrit®))

4. Identify and document the number of samples from each of the above locations to be included in the evaluation.
5. Identify and document the comparative method (or methods and models (tubes vs. cartridge systems)) for each department (different ACT analyzers or activators may be used within departments).
6. Identify and document the type of ACT activator and warming method utilized by each testing method. Discuss the differences that might be expected among activators (see table).

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>CPB</th>
<th>CPB (w Aprotinin)</th>
<th>PTCA/Stent</th>
<th>ECMO</th>
<th>Dialysis</th>
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<tr>
<td>Hemochron 401/801/8000/Response (NONWRM)</td>
<td>Celite (FTCA510)</td>
<td>Kaolin (FTKACT)</td>
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<td>Rapidpoint/TA S (PREWRM)</td>
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<td>Silica (ACT+)</td>
<td>Silica (ACT+)</td>
<td>Celite (LR-ACT)</td>
<td>Celite (LR-ACT)</td>
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</table>
7. Discuss the methodology differences between i-STAT ACT and comparative methods.

*Instrumentation:*
- Mechanical viscosity based end-point clot detection (hard blood clot)
- Biochemical based end-point detection (thrombin marker)

*Reagent:*
- High range versus low range version cartridges: different linearity and slopes in response to heparin
- Different activators (Celite versus kaolin versus silica): different linearity and slopes in response to heparin (although mostly similar)

8. Discuss the i-STAT analyzer’s screen displays (i.e. timer delay)
9. Identify with the account the expected differences in results and the “crossover” challenge

- The new NONWRM/PREWRM software for the i-STAT1 will help in comparison to the nonwarming Hemochron instruments. But there is still a great amount of variability in other ACT test systems, especially in CVOR (dilution, temperature, and operator). As such, please review the ACT VARIABILITY protocol to see if establishing the INCUMBENT device CV% would be a helpful data point for future understanding and data “equivalency”. Performing the ACT VARIABILITY protocol is recommended for CVOR verifications.

**PREPARATION PHASE**

1. How many cartridges are required?
   - How many samples are going to be run? Multiply this number by 2. Inform the customer of the need for and reason behind running samples in duplicate for both the i-STAT System and comparative methods.

2. How many patients need to be sampled? (we want as much diversity as possible for the study population. TEN various patients usually suffice.)

3. Are controls necessary to demonstrate precision?
   - If yes, how many replicates of each level? (i.e. for 20 replicates per level, allow 40 cartridges)

4. How many i-STAT Analyzers will be available? (minimum 2 required for duplicate testing)
   - This will assist in the number of controls that will need to be ordered. If only 2 analyzers are available and the customer wants to run 20 replicates of controls/level, then 2 boxes of each level of control will be exactly enough to run 20 replicates allowing NO outliers.
   - Note: 5 vials/box of controls and 2 levels available (level 1 and level 2)

5. How will duplicate samples be analyzed on the comparative method? For example, if the method is the Hemochron, do they have ones with dual wells or can we use 2 single well analyzers?
   - The Medtronic ACT/ACTII instruments run the samples in duplicate as part of their routine procedure (make sure to document BOTH replicates and not the Medtronic offered average ACT number).

6. Is a heparin linearity and precision validation required? If so, see the ACT Linearity Procedure for more details.
DATA COLLECTION PHASE

1. ENDPOINT:
   • To monitor a patient's Activated Clotting Time (ACT) using the i-STAT ACT test pre-, during and post CPB/procedure.

2. SUBJECTS/NEEDS:
   • A required minimum of 50 data points is recommended for this study if it is to include the Therapeutic Relation Chart. This includes a minimum 20 data points off-CPB (pre/post CPB) and a minimum of 30 data points on CPB or a minimum of 10 complete patient procedures (i.e., beating heart surgery, minimally invasive CPB, etc). Patients must meet the inclusion criteria outlined below. Patients will be categorized with regard to clinical outcome as diagnosed by an accepted clinical mode.
   • Existing ACT instrumentation (Actalyke™, Hemochron™, Medtronic, Rapidpoint)
   • ACT tubes (Actalyke™ C-ACT or K-ACT, Hemochron® FTCA510 or FTK-ACT) or ACT cartridges/cuvettes (Hemochron Jr. JACT+, Medtronic HR-ACT, Rapidpoint HMT)

Inclusion criteria:
   • Patients undergoing extracorporeal circulation
   • Patients undergoing interventional procedures (such as angioplasty) in which high dose heparin anticoagulation will be administered (over 1.5 u/ml heparin).
   • Patient histories must be taken as per the enclosed Data Collection Sheet (DCS). The history is to include all recent surgeries, other underlying conditions, family history etc.
   • All concomitant medications must be identified and recorded.
   • Clinical outcome must be reported on the Data Collection Sheet (DCS).

Potential exclusion criteria:
   • Patients who have established abnormalities (congenital or other) of their hemostasis system. If included in the study, the abnormality should be noted

3. PROCEDURE AND METHOD:

ALL SAMPLES ARE TO BE PERFORMED IN DUPLICATE

The following assessments must be recorded on the data collection sheet (DCS)
   • Patient demographics (age, sex, height, weight)  
   • Relevant medical history comprising:
      • Medical history (past 1 year)  
      • Predisposing medical history (e.g. recent catheterization; UA; MI)  
      • Concomitant medications

PRE-PUMP CORRELATION PROFILES
1. Pre-heparin (pre-sternotomy or post-sternotomy) “baseline” ACT should be performed
2. Draw a minimum of 5.0 ml of patient sample PRE-HEPARIN into a syringe and place the appropriate amount into each tube/cartridge. Record all data on the included Data Collection Sheets (DCS) sheets.
ON-PUMP ACT CORRELATIONS

Blood samples will be taken for the activated clotting time as follows:

Procedure for data collection:
1. Perform testing at the established testing frequency (i.e., 20 minutes)
2. Obtain patient sample
   a. Hemochron (test tube): collect a minimum of 5.0cc blood in a plain (unheparinized) plastic syringe (4.0cc for duplicate 2.0cc Hemochron tubes and less than 0.1cc for duplicate i-STAT ACT cartridges). Follow manufacturer’s recommendations for proper mixing and filling instructions
   b. Medtronic: collect minimum of 3.0cc blood in a plain, unheparinized plastic syringe (1.6cc for duplicate dual channel Hemotec cartridge and less than 0.1cc for duplicate i-STAT ACT cartridges). Follow manufacturers’ recommendations for proper mixing and filling instructions.
   c. Hemochron Jr/Rapidpoint/TAS: collect minimum of 1.0cc blood in a plain, unheparinized plastic syringe (0.2cc for duplicate cartridge/cuvette and less than 0.1cc for duplicate i-STAT ACT cartridges). Follow manufacturers’ recommendations for proper mixing and filling instructions.
1. Perform the tests.
   a. Simultaneously fill both i-STAT cartridges and both comparative analyzers’ tubes or cuvettes
   b. Immediately insert all cartridges and tubes/cuvettes into appropriate analyzers. Allow NO time delays
   c. At completion of test, use the enclosed data tracking form for data collection sheet (please be sure to use the specific data collection sheet for your established group). Record all subsequent data as well (additional heparin (amount), temp, hematocrit, etc.).
   d. If the result does not meet acceptable criteria, and a true reason is identified for not meeting the criteria, consider this an outlier and repeat the process with a fresh sample. Examples of outliers may include time delays between methods and/or instruments, mishandling of samples and heparinized samples.
   e. Repeat steps a-d for appropriate amount of samples

POST-PUMP CORRELATIONS PROFILES
1. Post-protamine “neutralized” ACT should be performed.
2. Draw a minimum of 5.0 ml of patient sample POST-PROTAMINE into a syringe and place the appropriate amount into each tube/cartridge. Record all data on the included Data Collection Sheets.
ANALYSIS PHASE

1. THE FOLLOWING CONDITIONS/TERMS MUST BE MET FOR ANALYSIS

DATA ANALYSIS
1. Site Demographics:
2. Patient Data Collection Sheet completed and submitted with traditional data sets
3. Instrument (reference) documentation
4. Reagent (reference) documentation
5. Method Comparison:
6. A minimum of 50 samples of each instrument/tube type in duplicate for both i-STAT and comparative analyzers is required. For CVOR, minimum 20 “off-pump” (pre or post pump or off-pump CPB) samples and minimum of 30 “on-pump” samples are required.

DATA SUBMISSION:
1. Completed ACT Data Collection Sheets
2. Submit ALL the information to i-STAT either electronically or ground mail
3. Contact person is Ann Parsons (aparsons@i-stat.com)
   i-STAT Corporation
   104 Windsor Center Drive
   East Windsor, NJ 08520
   phone 609-469-0214

*Allow 1.5 to 2 weeks to analyze the data, formalize the presentation package and mail the analysis to the customer (and or yourself/Abbott Sales Rep/PCS) as well as yourself (include addresses). When all necessary information is received, the analysis period will begin.*
HELPFUL TIPS

i-STAT ACT DO’s and DON’Ts

DO

• MAKE SURE THE i-STAT ANALYZER LAYS FLAT DURING ANALYSIS.
• FOLLOW ALL EXPLICIT INSTRUCTIONS FOR RECONSTITUTING CONTROLS AND RUNNING CONTROLS.
• USE ONLY PLASTIC (NON-HEPARINIZED) SYRINGES FOR COLLECTING SAMPLES. (GLASS SYRINGES WILL ACTIVATE THE CLOTTING PROCESS).
• FILL BOTH i-STAT CARTRIDGES AND THE COMPARATIVE ANALYZERS TUBES/CARTRIDGES AT THE EXACT SAME TIME AND RUN IMMEDIATELY.
• RUN ALL SAMPLES IN DUPLICATE FOR BOTH i-STAT AND COMPARATIVE INSTRUMENT.
• CHECK TO SEE IF ADDITIONAL ANALYZERS WILL BE NEEDED.
• INFORM THE CUSTOMER OF METHODOLOGY DIFFERENCES BETWEEN SYSTEMS.

DON’T

• MOVE THE i-STAT ANALYZER AT ANY TIME DURING THE TESTING PROCESS.
• ALLOW CUSTOMERS TO PERFORM THEIR OWN CORRELATION. IT’S VERY IMPORTANT THAT ON-SITE ASSISTANCE IS PROVIDED.
• DON’T USE BAM’S (BECAUSE OF NEED FOR DUPLICATE TESTING) AND BAM SOFTWARE REQUIREMENTS (REV. L AND HIGHER).
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CATH LAB: DATA COLLECTION SHEET

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<th>I-STAT #1</th>
<th>Reference #1</th>
<th>ACT (Sec)</th>
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<tbody>
<tr>
<td>I-STAT #2</td>
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<td>ACT (Sec)</td>
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- Reopro
- Aggrastat
- Integrilin
- Plavix
1 DEMOGRAPHICS

Site Name: ____________________________
Patient ID: ____________________________
Height: (cm) ____________________________
Weight: (kg) ____________________________
Sex: (M/F) ____________________________
Age: ____________________________
BSA: ____________________________

2 PRE-HEPARIN ACT DATA

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<th>Time</th>
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<th>Reference #1</th>
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<th>Est. Body Temp (C)</th>
<th>Hematocrit (%)</th>
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* If applicable

3 HEPARIN INFORMATION

Heparin Bolus Dose to Patient: (units)
Heparin Dose in Prime (Pump): (units)
Heparin Drip: (units/hr)

4 ON-PUMP ACT

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Protamine Dose Given: (mg) Time Given: ________________

5 POST-HEPARIN DATA

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<th>Ext. Venous Temp (C)</th>
<th>Hematocrit (%)</th>
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* If applicable

6 Notes

- □ Previous anti-platelet agents
- □ Surgery/Cath within 96 hours
- □ Blood products within 96 hours
- □ CPB within last 7 years
- □ Aprotinin used
- □ Heparin coated circuits used
- □ Previous heparin within 96 hours
- □ Mammary vessel harvested

7 Products

- □ Hemochron Serial/Model: ____________ □ i-STAT Instr. Serial/Model: ____________
- □ CA510 Lot number: ____________ □ Software/CLEW: ____________
- □ K-ACT Lot number: ____________ □ Celite ACT Lot number: ____________
- □ Kaolin ACT Lot number: ____________