TITLE: i-STAT ACT with Kaolin Cartridge Procedure

SYSTEM OVERVIEW:

The i-STAT 1 System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following primary components: Analyzer, Downloader/Recharger, Cartridges, Electronic Simulator and iSTAT DE and Telcor Quick Multi Link.

Analyzer

When a sample-filled i-STAT ACT Kaolin (ACTk) cartridge is inserted into the analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.

Downloader/Recharger

The Downloader/Recharger for the i-STAT Analyzer allows transmission of patient and quality control records from the analyzer to the QML software and also recharges the handheld.

Cartridges

The ACT Kaolin (ACTk) cartridge is a single-use disposable cartridge that contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well and the sample well is sealed before inserting it into the analyzer.

Electronic Simulator

The Electronic Simulator is used to verify the cartridge-reading performance of new or repaired analyzers. It simulates two levels or electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges.

iSTAT DE and Telcor Quick Multi Link

The i-STAT DE System and Telcor's Quick Multi Link (QML) provide the primary information management capabilities for the i-STAT system. All results are downloaded via the Downloader/Recharger to Telcor's Quick Multi Link (QML). Any results that do not meet expected criteria are flagged in QML and held for review by Point of Care. Note: the i-STAT DE system and Telcor's QML software are located at the Main Concord Hospital Laboratory-Point of Care office 250 Pleasant St, Concord NH 03301.

PRINCIPLE:

The i-STAT® Kaolin Activated Clotting Time test, ACTk, is a measure of the time required for complete activation of the coagulation cascade. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator –kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time.

CLINICAL SIGNIFICANCE:

The ACT is primarily used to monitor a patient's state of anticoagulation due to 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.

SPECIMEN:

Patient Preparation:

- *None*

Specimen Requirement:

The i-STAT ACTk test can be performed using venous or arterial samples.

- ACTk cartridge requires 40µL of whole blood for testing.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a plastic collection device (syringe).

- The collection device cannot contain anticoagulants such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Indwelling Line

- Fluid drip through the line must be discontinued.
- If blood must be drawn from an 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.
- Withdraw the sample for testing into a fresh plastic syringe.
- The collection syringe cannot contain anticoagulants such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

 All body fluids are handled as if capable of transmitting infectious diseases. Use Standard Precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

REAGENTS AND SUPPLIES:

Cartridges

Cartridges are sealed in individual pouches. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). Do not allow cartridges to freeze. Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). If the pouch has been punctured, the cartridge should not be used. Write date of receipt on boxes upon delivery of new cartridges. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

i-STAT Controls for ACT

Store at 2 to 8°C (35° to 46°F) until expiration date on the box.

Electronic Simulator

Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use. The Electronic Simulator test will fail if high humidity interferes with the measurements. Therefore it is not necessary to record humidity where the analyzers are in use.

CALIBRATION:

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type. Operator intervention is not necessary.

QUALITY CONTROL:

Daily Procedure

Analyzer Verification

The Internal Electronic QC and External Simulator verify performance of the analyzer. The Internal Electronic QC is scheduled to run each eight (8) hours of use. The "PASS" message will not be displayed on the analyzer screen. The "PASS" record will appear in the analyzer's stored results for transmission to QML. If the Internal Electronic Simulator "FAILS", run the External Electronic Simulator.

The analyzer may prompt the use of the External Electronic Simulator.

Action:

If PASS is displayed on the analyzer screen (after using the external Electronic Simulator):

- Remove the Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- Transmit results
- Use the analyzer as required

Remedial Action:

If FAIL is displayed on the analyzer screen for the Internal Electronic Simulator:

- Run the External Electronic Simulator. If PASS is displayed, use the analyzer as required.
- If the External Electronic Simulator FAILS, repeat the procedure with the same External Electronic Simulator.

If PASS is displayed, use the analyzer as required. If FAIL is displayed the second time:

- DO NOT analyze patient samples with the analyzer.

- Transmit results
- Notify Point of Care Specialists at x4645 or x4643. Request a loaner and send the faulty analyzer to Point of Care.

Procedure for testing cartridges with ACT Level 1 and Level 2 Controls:

When a new lot number of reagent/quality control arrives, the new and old lot numbers are run simultaneously, when applicable and results documented. When testing ACTk cartridges, controls should be used immediately after reconstitution. The contents of one vial may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 30 seconds of reconstitution. Immediately transfer the solution from the vial into a syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an analyzer. Results will display with PASS or FAIL. If all results are PASS, use the cartridges as needed.

Remedial Action:

If any results FAIL:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the Point of Care Specialist immediately at x4645 or x4643.

Procedure ACT Liquid Controls (perform once every 7 days)

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride ($CaCl_2$) vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
3. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
4. Use a syringe without anticoagulant to transfer the solution to an ACT cartridge.
5. Immediately seal the cartridge and insert it into a handheld. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Results will display as PASS or FAIL.

If any results FAIL:

- Repeat testing for failed level of QC; if the QC result is PASS, the instrument is available for patient testing.

- If the QC result is FAIL, use new vial(s) and repeat failed level of QC.
- If the QC results PASS, the instrument is available for patient testing. If not, do not perform any patient testing. Notify the Point of Care Specialist (x4645 or x4643) that the liquid QC is out of range and request Loaner device.

Review of Electronic (Internal & External) Simulator Results- Point of Care Specialist reviews results using the Telcor QML system. Acceptable results are noted. Unacceptable results are investigated and comments are made in QML.

Check Temperature Monitor- i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Integrity Testing on Receipt of Shipment

From each lot of ACTk cartridges received, use a representational number of cartridges to analyze ACT Level 1 and 2 Controls. When a new lot number of reagent/quality control arrives, the new and old lot numbers are run simultaneously, when applicable and results documented. Use any verified analyzer for control testing. Transmit the results to the Central Data Station. Use the expected values published on the Abbott Point of Care website (eVAS) to verify the integrity of the cartridges.

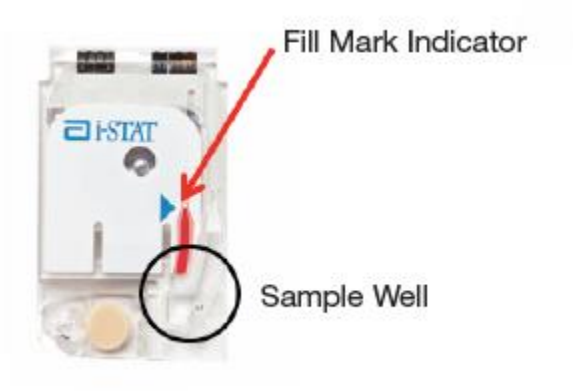
PROCEDURE FOR PATIENT ANALYSIS:

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Procedure for the iSTAT Analyzer:

1. Turn the analyzer on.
2. Press 2 for i-STAT Cartridge.
3. Scan or enter operator ID
4. Enter the patient's ID
5. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

6. Direct the dispensing tip containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.



7. Close the cover over the sample well until it snaps into place. DO NOT PRESS OVER THE SAMPLE WELL. Keeping your thumb or finger on the outside edge of the closure clasp, press the rounded end of the closure until it snaps into place. Ensure the cartridge is completely closed before inserting it into the device.

8. Insert the cartridge into the cartridge port until it clicks into place.

Note: For ACT testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

9. View results shown on the analyzer's display screen.

INTERPRETATION AND REPORTING RESULTS:

Calculations-

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

Displayed Results-

Results are displayed numerically with their units.

Suppressed Results-

There are three conditions under which the iSTAT System will not display results:

1. Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependent on the result of a test flagged as either > or <.

2. Cartridge results that are not reportable, based on internal QC rejection criteria, are flagged with ***.

   Action: Analyze the specimen again using a fresh sample and another cartridge. The results that are not suppressed should be reported in the usual manner.

3. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

   Action: Take the action displayed with the message that identifies the problem. Refer to the i-STAT 1 System Manual's Troubleshooting and call Point of Care Specialists x4645 or x4643.

Transmitting Results-

1. Results are transmitted wirelessly after two minutes of inactivity once a result is generated, unless a required field has not been completed.

2. Results are also transmitted by placing the analyzer in a Downloader/Recharger. If the analyzer is off it will turn itself on and send results to the Data Manager (Telcor QML).

3. Do not move analyzer while the message "Communication in Progress" is displayed.

Reference Ranges, Reportable Ranges

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT 1 System.

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE
Kaolin ACT	sec	74 – 137 (PREWARM)	74 – 137 (PREWARM)	100-700

Expected Ranges:

Coronary Artery Bypass >450 seconds
Cardiac Cath. 150- 300 seconds
Main Operating Room >200 seconds
Radiology / Special Procedures 150-250 seconds
Intensive Care Unit (ICU) 160-180 seconds (Impellas)
Progressive Care Unit (PCU) <170 seconds (Sheath removal)

Critical Results:

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse.

Cartridge Result Symbols:

***** Sensor Interference Detection**

< and/or > Outside Cartridge Reportable Range

↑ or ↓ Critical Value

Limitations of Procedure: *Interfering Substances*

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Kaolin ACT	Aprotinin (therapeutic)	200−280 KIU/mL	The i-STAT ^{Kaolin}ACT test is not significantly prolonged in the presence of a therapeutic level (200−280 KIU/mL) of aprotinin (Trasylol). If a patient has been administered the maximum aprotinin dosage of 400 KIU/ mL, APOC recommends that the first blood sample post administration be taken after 15 min to ensure the full distribution of the drug and to achieve a therapeutic plasma concentration.

Cleaning the Analyzer and Downloader

Clean the display and case with a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, alcohol or 10% bleach solution. Rinse with another pad moistened with water and dry.***Do not allow any fluids/liquids to get inside the cartridge port of the analyzer as this may impact the functionality of the internal electronics.***

References:

i-STAT ®1 System Manual; rev 28-AUG-19. Art: 714336-00P. Abbott Point of Care Inc.100 and 200 Abbott Park Road, Abbott Park, IL 60064 • USA

i-STAT ®1 Procedure Manual; rev 29-MAR-19. Art: 714446-00AA. Abbott Point of Care Inc.100 and 200 Abbott Park Road, Abbott Park, IL 60064 • USA

i-STAT User's Guide; rev. 17-APR-2020. Art: 726064-00O. Abbott Point of Care Inc.100 and 200 Abbott Park Road, Abbott Park, IL 60064 • USA