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DOCUMENT NUMBER:	SCPMG-PPP-0431
DOCUMENT TITLE:	Activated Clotting Time using i-STAT Analyzer
DOCUMENT NOTES:	

LOCATION:	SCPMG-rel	**VERSION:**	02
DOC TYPE:	SCPMG PPP	**STATUS:**	Release

EFFECTIVE DATE:	08 Aug 2022	**NEXT REVIEW DATE:**	08 Aug 2024
RELEASE DATE:	08 Aug 2022	**EXPIRATION DATE:**	

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Activated Clotting Time Using i-STAT Analyzer

Purpose

This procedure provides instructions for performing the i-STAT Celite Activated Clotting Time (ACT) test. The ACT test is an in vitro diagnostic test that uses fresh, whole blood used to monitor anticoagulation therapy in patients receiving heparin. ACT testing on the i-STAT 1 Analyzer ("i-STAT") is classified as a moderately complex, CLIA non-waived test.

Scope

This procedure may be performed by trained personnel approved to perform clinical laboratory tests as defined in Section 1206 of the California Business and Professional Code (Cal Bus & Prof Code) or per departmental policy whichever is more restrictive.

Policy

- The i-STAT 1 Analyzer will only be customized via the Data Exchange (DE) in Telcor QML by the POCT Coordinator to provide the primary information management capabilities
- An electronic check is performed automatically every 8 hours by the i-STAT internal simulator.
- Two levels of External Quality Control (QC) are tested with each new shipment and/or lot number of reagents, and at least every 8 hours of patient testing or at specified intervals found on a laboratory-established Individualized Quality Control Plan (IQCP).
- The i-STAT is customized to block testing when it fails the internal electronic simulator test. It is also customized to block patient and proficiency testing if scheduled QC requirements are not met.
- The i-STAT will be downloaded periodically to transmit results.
- Proficiency testing through CAP is analyzed 2 times a year.
- Instrument correlation is performed twice a year.
- Positive patient identification must be made using two unique identifiers prior to patient testing.
- Thermal probe and CLEW software updated are performed twice per year.

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Specimen sources and collection

- Testing must begin immediately after collection
  - Venipuncture and arterial punctures: Use plain plastic syringe without anticoagulant.
  - In-dwelling line: Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter, connectors, and needle.
- Sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.
- If a repeat test is needed, a fresh sample must be obtained

Specimen rejection

- Clotted samples
- Overfilled cartridges
- Blood collected above an IV line.

ACT Cartridges

The table below specifies storage requirements for the ACT cartridges.

Description	Storage	
i-STAT ACT Cartridges **Vendor:** Abbott	Refrigerated storage (2-8°C)	Store until expiration date. Do not use cartridges after the expiration date.
	Room temperature storage	Allow 5 minutes for a single cartridge to equilibrate to room temperature before opening pouches. Allow an entire box of cartridges to equilibrate to room temperature before use, approximately 1 hour. Cartridges may be stored at room temperature for 14 days. Do not expose to temperatures above 30°C. Do not return cartridges to the refrigerator after room temperature equilibration.
	After opening the pouch	Use cartridge immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Equipment

- i-STAT Analyzer 1
- i-STAT Downloader
- OMNI Print (portable printer)

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Safety Precautions

Handle i-STAT products using the standard safety precautions used when handling any potentially infectious material. Dispose of this product as biohazardous waste according to local, state, and national regulations.

Calibration

Internal calibration is automatically performed as part of the test cycle on each cartridge. Should the i-STAT Analyzer become inoperable for any reason, immediately contact the laboratory for a replacement i-STAT.

Electronic Simulator

Perform an electronic check on each handheld in use once a day with either the internal or external Electronic Simulator or as needed for regulatory compliance. The internal simulator check is initiated, every 24 hours or according to a customized schedule, when a cartridge is inserted into the cartridge port. If the internal simulator result is PASS, the cartridge test proceeds and the simulator results are stored. If FAIL is displayed for the internal simulator, reinsert the cartridge or use an external simulator.

Electronic Simulator Test	
Step	**Action**
1	Turn the handheld on by pressing the Power button.
2	Press Menu to access the Administration Menu.
3	Press **3** for Quality Tests.
4	Press **4** for Simulator.
5	Scan or enter Operator ID.
6	Enter the Simulator ID (serial number).
7	Insert the simulator into the cartridge port.
8	View results on the handheld's screen.
9	If PASS is displayed, continue to use the handheld.
10	If FAIL is displayed for the external simulator, reinsert the simulator. If FAIL is displayed for a second time, do not use the handheld and contact your Support Services representative.

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Quality Control

Quality control testing should be done to confirm that the i-STAT Analyzer 1 is working properly and providing reliable results. Only when controls are used routinely and the values are within acceptable ranges can accurate results be assured for patient samples.

Two levels of External QC are tested:

1. At least every 8 hours of patient testing or at specified intervals found on a laboratory-established IQCP.
2. With each new shipment and/or lot number of reagents.
    a. Run QC levels 1 and 2 using the current lot number and on the new lot number of cartridges.
    b. Record all results on the appropriate logsheet.
    c. Compare results for each level; results must correlated within Allowable Total Error (20%) before the new lot is put in use.

Description	Storage	
ACT Quality Control, Level 1 and Level 2	Refrigerated storage (2-8°C)	Store unopened until expiration date.
	Room temperature storage (15-25°C)	Allow vials to equilibrate to room temperature for 45 minutes from refrigerated storage prior to reconstitution. Controls may be stored at room temperature for up to 4 hours prior to reconstitution.
	After reconstitution	Reconstitute one control level at a time and use immediately (within 30 seconds) after reconstitution and mixing steps.

Quality Control Testing Procedure	
Step	**Action**
1	Program the test: a. Press the ON/OFF key.  b. Press the **Menu** key.  c. Press **3** to select Quality Tests. d. Press **1** to select Control. e. If applicable, select QC Event screen, press **2** for Scheduled. Press **1** for Unscheduled. f. Select the cartridge type **1-ACT-C** to be run. g. Select fluid type to be run. Select **1-APOC** for Abbott Point of Care liquid controls. h. Enter/scan Operator ID. i. Scan Control Lot Number.

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	j. Scan Cartridge Lot Number
2	Remove the cap from one vial of calcium chloride reconstituting fluid and the stopper from one lyophilized human plasma control vial.
3	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial.
4	Allow the vial to sit at room temperature for 1 minute.
5	Mix the contents of the vial by swirling for 1 minute, then inverting slowly for 30 seconds. Run the sample immediately after mixing. **Note**: Avoid vigorous or rapid mixing to minimize foaming. Visually inspect the control vial to ensure that it is fully reconstituted.
6	Using a plastic transfer pipette, immediately transfer the sample into the test cartridge and seal the cartridge.
7	Insert the cartridge into the i-STAT.
8	The numeric QC result is displayed on the screen with a “Pass” or “Fail” status.
Note: If results fail, do not test patients. Check the cartridges and repeat testing. Document on the i-STAT Corrective Action log.	

Before you begin

The i-STAT Analyzer 1 must remain on a level, vibration-free surface with the display facing up during testing. A level surface is also required when running the handheld int the downloader/recharger. The analyzer should remain level until a result is obtained.

All cartridges should remain in pouches until time of use. Use cartridges immediately after removing from its protective pouch. Do not contaminate the contact pads on the cartridges. Do not apply pressure to the central area of the label where the calibrant pack could pre-burst.

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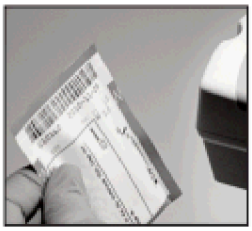
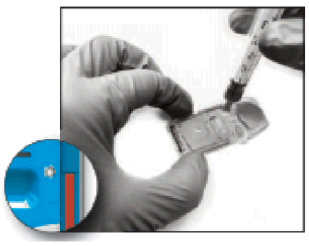
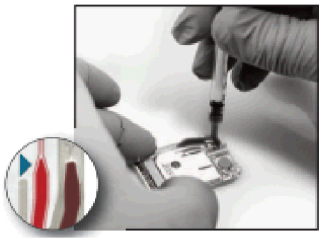
Procedure Follow the steps below to perform patient testing on the i-STAT Analyzer 1.

Patient Test Procedure	
Step	**Action**
1	Turn the handheld on by pressing the Power button.
2	Press **2** i-STAT Cartridge
3	Follow handheld prompts.
4	Scan the lot number on the cartridge pouch. a. Position barcode 3-9 inches from scanner window on the handheld. b. Press and hold SCAN to activate the scanner. c. Align the red laser light so it covers entire barcode. d. The handheld will beep when it reads the barcode successfully. 
5	Continue normal procedures for preparing the sample, filling, and sealing cartridge. a. Remove cartridge from its pouch. Avoid touching contact pads or exerting pressure over the calibrant pack in the center of the cartridge. b. Direct the dispensing tip into the sample well and dispense sample until it reaches the fill mark on the cartridge. c. Close the cover over the sample well until it snaps into place. Do not press over the sample well.  
6	Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.
7	Review results and record results accordingly.

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Reporting of Results

- Patient and internal procedural QC results must be recorded on the Patient Logs/Forms or directly in KP Health Connect or per facility requirement.
- Use DocFlow sheets for inpatient results in KP Health Connect.

To transmit results:

1. Dock the analyzer in the Downloader/Recharger.
2. When properly seated, the red light will turn on and the analyzer will automatically transmit all unsent results.
3. Do not move the analyzer while "Communication in progress" is displayed. If transmission is unsuccessful, contact your local Point-of-Care Coordinator (POCC).

To enter patient results in KP Health Connect (KPHC):

1. Log in to KPHC. Select EPIC, then select Hospital Chart.
2. Enter the patient's medical record number. Select Accept.
3. Select Flowsheet, then select Point of Care Testing.
4. Type "ISTAT" in the search box, then scroll down to find line 544/545 ACT (Mod Complex according to age group).
5. Type the patient result in. Review results entered. Select Accept.

For unexpected results, when results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. Refer to the i-STAT Technical Bulletin Analyzer Coded Messages.

Result Unable to be Displayed	Action
Results outside the system's reportable range are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively.	Repeat test with new specimen.
Cartridge results that are not reportable based on internal QC rejection criteria are flagged with ***.	Repeat test with new specimen.
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.	Take the action displayed with the message that identifies the problem.
Call Abbott Technical Support or your local POCC if problem is not able to be resolved. Document all corrective actions taken.	

Reportable Range

ACT Reportable Range: 50-1000 seconds

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Preventive Maintenance

Inspect and clean the exterior of the instrument as needed. Clean the display screen and the case using a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap & water, alcohol, 10% bleach solution or PDI Super Sani-Cloth. Wipe the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam between the display screen and the case. Inspect and clean the Downloader as needed.

Limitations and Interferences

- An interferent is a substance that, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.
- Glass containers used for collection may accelerate clotting times.
- Aprotinin may prolong clotting times. The test is not recommended for use with patients receiving aprotinin.
- Platelet dysfunction may affect the results of the test.
- Insufficiently flushed lines may introduce interfering substances
- The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37ºC.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- Procedure Manual for the iSTAT System
- i-STAT 1 User Guide, Abbott Point of Care
- i-STAT Technical Bulletin Analyzer Coded Messages
- i-STAT Celite Activated Clotting Time (Celite ACT)

Controlled Documents

The following controlled documents support this procedure.

Documents
i-STAT ACT Verification Plan
i-STAT ACT Training and Competency Assessment

Technical Support

The manufacturer provides a toll-free line for technical support at **1-800-366-8020** or contact your local POCC.

Signature Manifest

Document Number: SCPMG-PPP-0431 **Revision:** 02
Title: Activated Clotting Time using i-STAT Analyzer
Effective Date: 08 Aug 2022

All dates and times are in Pacific Standard Time.

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New Document or Change Request

Name/Signature	Title	Date	Meaning/Reason
Jonathan Lee (T330974)	Practice Leader	19 Jul 2022, 01:38:36 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Jonathan Lee (T330974)	Practice Leader	19 Jul 2022, 01:41:58 PM	Complete

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Laura Gabrys (G157770)	DIR OPER AREA LAB	20 Jul 2022, 01:56:54 PM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Sajjad Syed (M401383)	Chief of Laboratory/Pathology	08 Aug 2022, 10:59:49 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Jonathan Lee (T330974)	Practice Leader	08 Aug 2022, 11:13:41 AM	Approved

Notify Trainers

Name/Signature	Title	Date	Meaning/Reason
Precious Joy D Cabasal (W413921)	Preanalytical Manager	08 Aug 2022, 11:13:42 AM	Email Sent
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