



CLINICAL MANUAL

Guideline/Standard Operating Procedure

TITLE: Abbott i-STAT Operating Procedure – Point of Care Testing (POCT)	NUMBER: 632
Sponsor: Children’s Health Program Managers	Page: 1 of 13
Approved by: Policy and Practice Committee	Approval Date: May 11 th 2021 Effective Date: Sept 9 th 2021
Applies To: All certified health care professionals performing patient testing using the Abbott i-STAT within IWK Health Centre	

PREAMBLE

The Activated Clotting Time (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 used in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, and extra-corporeal circulation during bypass. This procedure provides information and instruction required to perform testing using the Abbott i-STAT.

POLICY STATEMENTS

1. Safety precautions and infection prevention and control policies (IWK # [201.1 Application of Routine Practices](#)) must be adhered to when taking patient blood samples for point of care testing (POCT).
2. Patient identification policies must be adhered to in order to ensure clients receive the service or procedure intended for them (IWK # [1100 Patient Identification](#)).
3. I-Stat users must be certified and be competent in POCT (IWK # [3101 Point of Care Testing](#)).
4. Consistent inventory management practices, e.g., labelling of supplies and inventory stock rotations are paramount to ensure quality POCT results and patient safety.
5. Testing must have an approved Health Care Provider order or care directive (Appendix A-definitions).
6. Liquid quality control (QC) for ACT will be performed by the Point-of-Care coordinator or designate. Liquid QC will be performed monthly and when a new lot number of cartridges is received. (See Appendix C: Liquid Quality Control Procedure).

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

- 7. CLEW software update as required (every 6 months) will be performed by the Point-of-Care coordinator or designate. (See Appendix F: CLEW Software Update).
- 8. Results must be charted indicating POC ACT result, unit of measure (seconds), initials of person performing the test, the date and time of sample collection/testing.

GUIDELINES/SOPs

Performing Patient Testing:

Note the following testing precautions:

Equipment and supplies

- **Do not use the cartridge if the pouch has been punctured**
- **Do not contaminate the contact pads with fingerprints or talc from gloves**
- **Do not apply pressure to the central area of the label (calibrant pack inside could burst). Handle cartridges by the sides.**
- **Never attempt to remove a cartridge while “Cartridge Locked” message is displayed**
- **Keep the cartridge level while applying sample**
- **Place instrument on a flat and stable surface at all times**
- **Store the device on the Downloader/Recharger after each use to ensure it is always charged. Place the instrument in the recharger if it displays “Low Battery”**

Patient Sample

- Avoid exposing the sample to air and time delays in filling the cartridge
- Filling of cartridge should be continuous

Kaolin ACT Patient Testing:
1. Remove cartridge from refrigerator and warm for 5 minutes
2. Press the On/Off key to turn on the device
3. Select number two (2) “i-Stat Cartridge”
4. Manually enter Operator ID (if applicable) or press enter to bypass
5. Scan patient ID barcode (or manually enter account number/K number)
6. Using two unique identifiers, identify patient and collect whole blood in a plain (no anticoagulant) syringe.

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

7. Scan barcode or manually enter cartridge lot number from outside of pouch.
8. Remove the cartridge from pouch
9. Place the tip of the syringe into the cartridge well and fill the cartridge to the fill line
10. Carefully close the cover over the sample well, and insert the cartridge into the device until it “clicks” in place. “Cartridge Locked” will be displayed.
11. Keep device on a level surface during testing and wait for results to appear
12. Disinfect analyzer with Hospital Approved Disinfecting wipes once testing is complete. Place Analyzer in downloader/recharger.

Reagents/Supplies/Equipment

Kaolin ACT Cartridges are stable refrigerated (2-8°C) until the manufacturers expiration date. Once at room temperature a **14 day expiration** must be written on the cartridge (or box of cartridges). Keep cartridges in pouch until time of use.

Note: Avoid exposing cartridges to temperatures above 30°C. Do not allow cartridges to freeze.

The Electronic Simulator is stored at room temperature. When not in use the Electronic Simulator should be in its protective storage box with the plastic cap covering the electronic contacts (See Appendix E: Electronic Simulator Procedure).

Resulting Patient Test Results

NOTE: Review results for errors or flags. Document results.

***	Results are not reportable This could be due to interfering substances or improper handling of cartridges. Repeat testing using another cartridge.
< and >	Results are above or below reportable range. Report as such
Reportable Range	50-1000 seconds
Reference Range	74-137 seconds (Prewarmed)

Note: Expected Values: Target ACT values are based on procedure, patient demographics, disease state and physician discretion. The clinical team will establish the optimal ACT target value for each patient.

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

Troubleshooting	See Appendix D or refer to Operator’s Manual for any flags
-----------------	------------------------------------------------------------

REFERENCES

Abbott Point of Care (2014). Abbot i-STAT Manual. Princeton, NJ 08540
<https://www.abbottpointofcare.com/support/technical-documentation/istat-system-manuals>

RELATED DOCUMENTS

Policies

IWK - 3101 Point of Care Testing

IWK - 1100-Patient Identification

IWK - 201.1 Application of Routine Practices

IWK - 1753-Arterial Line, Blood Sampling and Removal

Appendices

Appendix A - Definitions

Appendix B – Sample Requirements and Rejection

Appendix C - Liquid Quality Control Procedure

Appendix D - Troubleshooting

Appendix E - Electronic Simulator Procedure

Appendix F - CLEW Software Update

Appendix G - Printing Results and Changing Paper (if equipped)

Appendix A: Definitions

Kaolin Activated Clotting Time (ACTK) is an in vitro diagnostic test that uses fresh, whole blood, and is used to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

Point-of-Care (POC): Near to or at the site of the patient/client.

Point-of-Care Testing (POCT): Testing performed outside a central laboratory environment, by authorized health care personnel, generally nearer to, or at the site of the patient/client, with the result leading to possible change in the care of the patient.

Point of Care Interdisciplinary Committee (POCIC): Includes individuals from laboratory, nursing and other services as required. It operates according to its Terms of Reference to define the scope of POCT, establish competency requirements, approve a training program and monitor the delivery of quality POCT.

Quality Control: The set of procedures designed to monitor the test method and the results to assure test system performance by detecting gradual or sudden changes in performance.

Healthcare Professional Delivering Point of Care Testing: A professional recognized as qualified by the appropriate professional association and pursuant to the professional legislation in force, following appropriate training, to perform the duties of collecting clinical samples and determining the result of POCT as well as counseling the client if necessary. This healthcare professional may be a physician, medical technologist, registered nurse, licensed practical nurse, dietician, pharmacist, or pharmacist technician provided they are members of their required professional health associations and have received appropriate training.

Care directive: A care directive is an organizational policy developed in consultation with prescriber(s) for an intervention or series of interventions to be implemented by another care provider for a range of clients with identified health conditions or needs when specific circumstances exist. The purpose of a care directive is to provide safe, timely, effective and efficient client care and to optimize the practice of all care providers. An example of a care directive is a policy that would enable a nurse to administer influenza vaccines to all first-year nursing students in a nursing program within a specific time period. Nova Scotia College of Nurses (2018)

Appendix B: Sample Requirements and Rejection

ACT Specimen	<ul style="list-style-type: none">• Fresh arterial or venous whole blood collected into a plastic syringe/tube containing NO ANTICOAGULANT• Dispense immediately into cartridge• 40µL of blood is required to fill the cartridge
Sample Rejection	Reject sample if: <ul style="list-style-type: none">• There is evidence of clotting• An anticoagulant was used

Appendix C: Liquid Quality Control Procedure

Table 1: Liquid Quality Control for i-STAT

Control	Level	Stability	Frequency	Preparation
ACT Controls	Level 1 and 2	<p>Unopened:</p> <p>Stable at 2 to 8°C until the manufacturer expiration date</p> <p>Once reconstituted controls must be run within 30 seconds.</p>	<p>Once a month</p> <p>Every new lot number</p> <p>After a CLEW software update</p>	<p>Allow to come to room temperature for 45 minutes.</p> <p>See Liquid Quality Control procedure for reconstitution instructions below.</p>

Liquid Quality Control Procedure

Preparation of i-STAT Analyzer
1. Remove i-STAT from charging base. Turn on.
2. Press “Menu” Key to access Administration Menu.
3. Choose Quality Tests (#3). Choose Control (#1).
4. Scan barcode or manually enter Operator ID (if Applicable – press enter to bypass)
5. Scan barcode or manually enter the control lot number on the vial of control
6. Scan barcode or manually enter Cartridge lot number
Preparation of ACT Controls
<p>Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials. Only reconstitute one vial at a time to ensure immediate testing.</p>
1. After 45 minutes at room temperature, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. Add the entire contents of the calcium chloride vial into the lyophilized control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out. |
| 3. Allow the vial to sit at room temperature undisturbed for 1 minute. |
| 4. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. |
| 5. Immediately transfer the solution from the vial using a syringe, into the Kaolin ACT cartridge. Carefully close the cover over the sample well and insert cartridge into the ready device. |
| 6. Once testing is complete a results will display in seconds. |

Interpretation Liquid Quality Control Results

Control results should fall within the expected ranges. Ranges are found on the Value Assignment Sheets (VAS) specific for each lot number. VAS display target values and ranges expected when cartridges, controls and equipment are performing properly.

Appendix D: Troubleshooting

Troubleshooting for testing

1. Repeat testing using a fresh sample and use a new cartridge if questioning the integrity of the sample
2. Run the Electronic Simulator test to make sure the analyzer is functioning.
3. Send the instrument to the lab along with a description of the problem or any error messages displayed. (Refer to i-STAT user manual to troubleshoot messages).

Troubleshooting for Liquid Quality Control

Verify the following conditions are met and then repeat the test:

1. Correct expected values are used i.e. matches control lot, cartridge lot and software (CLEW) version
2. Expiration date printed on cartridge pouch and control ampoule or vial have not been exceeded (Reminder 14day expiry on cartridge if at room temperature)
3. Cartridge and control have been stored correctly. The control has been handled correctly.
4. The device being used passes the Electronic Simulator test (See Electronic Simulator procedure Appendix E)

Appendix E: Electronic Simulator Procedure

Electronic Simulator Procedure
1. Remove i-STAT from charging base. Turn on.
2. Press “Menu” Key to access Administration Menu.
3. Choose Quality Tests (#3). Choose Simulator (#4).
4. Scan barcode or manually enter Operator ID (if Applicable – press enter to bypass)
5. Scan barcode or manually enter the lot number on the Electronic Simulator
6. Remove the plastic cap on the simulator and insert into the i-STAT. “Simulator Locked” will appear and a 120second countdown will begin
7. Results PASS or FAIL will be displayed once testing is complete. If PASS is displayed continue with patient testing. If FAIL is displayed allow the i-STAT to settle for 15 minutes and repeat testing.
8. Remove the electronic simulator and replace the plastic cap. Store in a provided box in a dry place.
Note: Electronic Simulator must be run once per day of use to ensure proper functioning of the i-STAT.

Appendix F: CLEW Software Update

CLEW Software Update Procedure
<p>1. Log into computer and navigate to: http://www.point.of.care.abbott/int/en/offerings/support/i-stat/istat-system-software-update Enter point of care username and password (contact POCC if required)</p>
<p>2. Connect i-STAT USB cable to downloader and computer</p>
<p>3. Select Language from the drop down menu.</p>
<p>4. Click the link “Download software file for users with no data management system”</p>
<p>5. When prompted click on the software file line and click RUN (twice). A command window opens prompting to overwrite, answer “Y” and then press Enter. Continue answering “Y” until the Command window closes.</p>
<p>6. Open the JammLite Icon on the desktop</p>
<p>7. In the JammLite Utility, select the i-STAT 300 Analyzer within the Instrument dropdown menu.</p>
<p>8. By default the lowest numbered COM port will automatically be selected. A prompt will appear if the incorrect port is selected once update starts (change the COM port if necessary)</p>
<p>9. Check that the Application and CLEW listings match those in the Product Update.</p>
<p>10. Press Update and follow the onscreen instructions:</p> <ol style="list-style-type: none"> 1. If the analyzer is already in the downloader remove it 2. Ensure the Analyzer to be updated is off 3. Place the analyzer in the downloader
<p>11. Do not move the i-STAT until the successful screen is displayed</p>
<p>12. To update another i-STAT repeat steps 10-11.</p>
<p>13. Once all analyzer are updated, exit out of JammLite Utility and unplug USB cable.</p>
<p>14. Run the Electronic Simulator (See Appendix E)</p>
<p>15. Run Liquid Quality Controls (See Appendix C)</p>

Appendix G: Printing Results and Changing Paper (if equipped)

Printing results from Data Review
<ol style="list-style-type: none">1. Turn on the device2. Press the Menu Key3. Press Data Review (#2)4. Press List (#7)5. Find the required record by scrolling through the test records using the ← and → keys to change the page.6. Press the numbered key for the test records(s). If required, press the numbered key again to deselect and cancel print request.7. Align the device and printer IR window.8. Press the print button
Changing the Paper
<ol style="list-style-type: none">1. Remove any remaining paper by pulling up the paper window to open the paper compartment<ol style="list-style-type: none">a. Remove the old roll.b. Unroll a few centimeters from the new roll, place it inot the compartment with the paper protruding from the compartmentc. Snap the door closed.d. Press the paper feed button to ensure proper functioning. <p>Note: The paper should be rolling off from the bottom of the roll.</p>
<p>Note: If the device is moved away from the printer, printing will stop; re-align IR and press print again to re-print a complete report.</p>

* * *

District Health Authority/IWK Policies Being Replaced

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)