UPMC PINNACLE
POLICY AND PROCEDURE MANUAL

POLICY:
INDEX: Point of Care Testing

SUBJECT: Activated Clotting Time (Kaolin-activated) on the Abbott i-STAT 1 Analyzer

I. POLICY

It is the policy of UPMC Pinnacle that activities of the POCT program comply with all current standards for laboratory accreditation, regardless of the scope of testing.

II. PURPOSE

The purpose of this policy is to provide the steps necessary to run an Activated Clotting Time (Kaolin-activated) on the Abbott i-STAT 1 Analyzer.

The principle of the test and its intended use can be found in the Abbott Cartridge and Test Information Sheet for Kaolin ACT.

III. SCOPE

This policy applies to the following UPMC Pinnacle hospital facilities:

☒ UPMC Pinnacle Hospitals (UPMC Pinnacle Harrisburg, UPMC Pinnacle Community Osteopathic, and UPMC Pinnacle West Shore
☐ UPMC Carlisle
☒ UPMC Memorial
☒ UPMC Lititz
☒ UPMC Hanover
☐ UPMC Pinnacle owned or controlled entities

IV. DEFINITIONS (optional)

1. ACT-K = Activated Clotting Time (Kaolin-activated)
2. POCT = Point of Care Testing
3. QC = Quality Control

V. PROCEDURE

1. Materials and Equipment
    a. Abbott i-STAT 1 Analyzer
        i. Operating temperature range is 16 to 30° C.
        ii. Must be on a stable, flat, level surface (downloader is appropriate) and not moved while a test is being performed.
    b. Abbott i-STAT 1 Analyzer ACT-K cartridge (Abbott P/N 03P87-25)
        i. Must be at room temperature before using.
            1. If an entire box of cartridges is removed from the refrigerator, the box must sit at room temperature for 1 hour before using.

2. If individual cartridges are removed from the refrigerator, they must sit at room temperature for 5 minutes before using.

ii. Stable until the expiration date on the box or cartridge pouch when stored at 2 to 8° C. Cartridges that have passed this expiration date are to be discarded.

iii. Stable for 14 days or until the expiration date on the cartridge pouch (whichever comes first) when stored at room temperature. Boxes or individual cartridge pouches must be labeled with their new expiration date if the expiration date changes once removed from the refrigerator. Cartridges that have passed this expiration date are to be discarded.

1. Cartridges should not be returned to the refrigerator once they have been at room temperature.
2. Cartridges should not be exposed to temperatures above 30° C. Cartridges that have been exposed to temperatures above 30° C are to be discarded.

c. Abbott i-STAT 1 Analyzer ACT Control Level 1 (Abbott P/N 06P17-15) and Level 2 (Abbott P/N 06P17-16)

i. Stable until the expiration date on the box or vial when stored at 2 to 8° C. Control materials that have passed this expiration date are to be discarded.

ii. Stable unreconstituted for 4 hours at room temperature. Unreconstituted control materials that have been at room temperature for longer than 4 hours are to be discarded.

iii. Stable reconstituted for 30 seconds. Control materials are to be discarded 30 seconds after reconstitution is completed.

d. Plastic Syringes – store and use according to manufacturer's instructions.

2. Specimen
   a. Fresh whole blood without anticoagulant collected in a plastic syringe or a plastic tube without clot activators or serum separators.
   b. Test samples for ACT immediately.
3. Calibration – no calibration is performed by the end user. Info regarding calibration can be found in the i-STAT 1 System Manual.
4. Quality Control – acceptable QC results are to be obtained for all QC testing before patient testing can be performed.
   a. The internal simulator is automatically performed by the analyzer every eight hours of use. No action is required by the operator. If the internal simulator fails, no result will be obtained for the cartridge. Info regarding the internal simulator can be found in the i-STAT 1 System Manual.
   b. Abbott i-STAT 1 Analyzer ACT Control Levels 1 and 2 are run at intervals defined by each facility:
      i. UPMC Pinnacle Harrisburg, UPMC Pinnacle West Shore, UPMC Lititz, and UPMC Memorial hospitals – run once per week.
      ii. UPMC Carlisle – run once every 4 weeks
      iii. UPMC Hanover – run once every 30 days.
   c. Control reconstitution instructions:
      i. Remove vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid from the refrigerator and allow them to stand at room temperature for 45 minutes.
      NOTE: Both vials for level I will be labeled with the number 1 and

both vials for level 2 will be labeled with the number 2. For the next two steps, please be sure both bottles have the same number on them.

ii. Remove the cap and stopper from one lyophilized plasma vial and one $CaCl_2$ reconstituting fluid vial.

iii. Pour the entire contents of the $CaCl_2$ reconstituting fluid vial into the lyophilized plasma vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.

iv. Allow the vial to sit at room temperature for 1 minute.

v. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds.
NOTE: To minimize foaming of the control sample, avoid rigorous 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.

vi. Using a plastic transfer pipette or plastic syringe, immediately transfer the solution from the vial into the ACT-K cartridge.

d. Procedure for running Abbott i-STAT 1 Analyzer ACT Control Levels 1 and 2:

i. Please use universal precautions and follow all policies and procedures for handling potentially infectious materials.

ii. Turn analyzer on.

iii. Select the MENU key.

iv. Select #3 - QUALITY TESTS

v. Select #1 – CONTROL

vi. Scan your operator ID by holding the SCAN key down and centering the laser reader on the barcode on your employee badge. For those with a KRONOS barcode on their badge, the KRONOS barcode is to be scanned.

vii. Select #1 – APOC

viii. Select #1 for Level 1 or #2 for Level 2

ix. Scan the control lot number from the side of the control vial.

x. Scan the cartridge lot number from the cartridge pouch.

xi. Reconstitute the appropriate control following the reconstitution instruction in section V. 4. C. of this procedure.

xii. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

xiii. Direct the syringe containing the control fluid into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.

xiv. Immediately close the cover over the sample well until it snaps into place. (Do not exert excess pressure on the cover.)

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

1. The operator should never attempt to remove a cartridge when the “cartridge locked” message is displayed on the analyzer screen.
2. In order to terminate a test which has already begun, wait until “Test in Progress” appears on the screen and choose #1 for Stop Test, choose #1 for “yes” and the analyzer will

display a “Stopping Test” message. Once the “Cartridge Locked” message is no longer displayed, the cartridge can be removed from the analyzer.

xvi. View results (PASS or FAIL) shown on the analyzer’s display screen.
xvii. Repeat the process for the other level of control.
xviii. Dispose of contaminated cartridges and other non-sharps material into an approved biohazard waste container.
xix. Patient tests are not to be run unless a result of PASS is obtained for both levels of control.

5. Patient Test Procedure
    a. Please use universal precautions and follow all policies and procedures for handling potentially infectious materials.
    b. Turn i-STAT 1 Analyzer analyzer on.
    c. Select #2 – i-STAT 1 Analyzer cartridge.
    d. Scan operator ID by holding the SCAN key down and centering the laser reader on the barcode on your employee badge. For those with a KRONOS barcode on their badge, the KRONOS barcode is to be scanned.
    e. Scan patient ID.
    f. Verify the patient’s ID using the Positive Patient ID feature.
    g. Scan cartridge lot number from the cartridge pouch.
    h. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibration pack in the center of the cartridge.
    i. Direct the syringe 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.
    j. Close the cover over the sample well until it snaps into place. (Do not exert excess pressure on the cover.)
    k. Insert the cartridge into the cartridge port until it clicks into place.
        i. The operator should never attempt to remove a cartridge when the “cartridge locked” message is displayed on the analyzer screen.
        ii. In order to terminate a test which has already begun, wait until “Test in Progress” appears on the screen and choose #1 for Stop Test, choose #1 for “yes” and the analyzer will display a “Stopping Test” message. Once the “Cartridge Locked” message is no longer displayed, the cartridge can be removed from the analyzer.
    l. View results shown on the analyzer’s display screen.
    m. Dispose of contaminated needle and syringes in a sharps container. Dispose of contaminated cartridges and other non-sharps material into an approved biohazard waste container.
6. Reference Range
    a. 74 to 137 seconds.
    b. Procedural ranges:
        i. For purposes of removing catheters, the ACT result should be less than baseline level or less that 150 seconds (whichever is greater) before the catheter is removed. If the result is greater than baseline or 150 seconds (whichever is greater), the catheter should not be removed unless the physician is notified and a new order is written.
        ii. i-STAT 1 Analyzer Kaolin ACT values should be greater than or equal to 480 seconds for on-pump coronary bypass surgery.

iii. i-STAT 1 Analyzer Kaolin ACT values should be greater than or equal to 350 seconds for off-pump coronary bypass surgery.
iv. i-STAT 1 Analyzer Kaolin ACT values should be greater than or equal to 250 seconds for Transcatheter Aortic Valve Implementation (TAVI) procedures.
v. PTCA procedures at Lititz
    1. i-STAT 1 Analyzer Kaolin ACT values should be 200-250 if Glycoprotein IIb/IIIa Inhibitors are used during procedures in the Invasive Cardiac and Vascular Lab.
    2. i-STAT 1 Analyzer Kaolin ACT values should be 250-300 if Glycoprotein IIb/IIIa Inhibitors are not used during procedures in the Invasive Cardiac and Vascular Lab.

7. Preventive Maintenance/Troubleshooting
    a. If the analyzer is placed onto a wet surface or if any liquid is spilled onto it, dry the analyzer immediately.
    b. If cleaning of the analyzer is necessary, the display screen and case can be cleaned with any of the following:
        i. Alcohol
        ii. 10% bleach solution
        iii. PDI® Super Sani-Cloth®
    c. Twice a year the thermal probes are to be checked. Refer to the i-STAT 1 System Manual for additional info.
    d. Refer to the i-STAT 1 System Manual for additional info regarding maintenance and troubleshooting.
8. Limitations
    a. Reportable range for the ACT-K is 50 to 1000 seconds.
    b. Result of *** is invalid and the test must be repeated with a new sample.
    c. Refer to the Abbott Cartridge and Test Information Sheet for Kaolin ACT and the i-STAT 1 System Manual for other limitations of the test and analyzer.

VI. DOCUMENTATION

1. All results are reported in seconds.
2. Results less than 50 seconds are reported as <50 seconds.
3. Results greater than 1000 seconds are reported as >1000 seconds.
4. Quality control test results are automatically transferred to and stored in the POCT data management system.
5. Patient test results are automatically transferred to the patient's EMR.

VII. ATTACHMENTS

N/A

VIII. REFERENCES

1. Abbott Cartridge and Test Information Sheet for Kaolin ACT. Latest version available via external link in MCN.
2. i-STAT 1 System Manual. Latest version available via external link in MCN.

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Approved By:	Thomas Wilson, Lead Med Tech POC; Jacob Gildea MD, Med. Dir. WS and CR POC; Yanping Li MD, Med. Dir. HH and CGOH POC; Cindy Sturtz MD, Med. Dir. Hanover POC; Kraig Sturtz MD, Med. Dir. MEM POC; Mariah McCready MD, Med. Dir. Lititz POC
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