KAISER PERMANENTE®
COLORADO LABORATORY

Abbott i-STAT
FINGERSTICK INR PROCEDURE

PRINCIPLE

This procedure outlines the use of whole blood in the determination of prothrombin time which is used for monitoring oral coagulation (warfarin) therapy. The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when activated with a thromboplastin.

In a prothrombin time test, coagulation is initiated by mixing the sample with tissue thromboplastin. In traditional prothrombin time tests, complete activation is indicated when actived thrombin converts fibrinogen to fibrin and extensive or localized clots are detected manually or optically. The i-STAT PT/INR test is similar but the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion.

The added thrombin substrate is H-D-phenylalanyl-pipecolyl--arginine-pmethoxydiphenylamine. Thrombin cleaves the amide bond at the carboxy terminus of the arginine residue (two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The electrochemical compound resulting from this cleavage of the H-D-phenylalanyl-pipecolyl--arginine-pmethoxydiphenylamine is detected amperometrically and the time of detection is measured.

INTENDED USE

The i-STAT PT/INR is an in vitro diagnostic test intended for quantitative prothrombin testing for monitoring of oral anticoagulant therapy using fresh capillary or venous whole blood samples. The i-STAT PT/INR is NOT intended for evaluating individual factor deficiencies. The i-STAT PT/INR test is to be used by a trained and certified health care professional in accordance with the facility's policies and procedures.

SCOPE

This test is only performed at Highlands Ranch and Westminster clinics.

SPECIMEN REQUIREMENTS AND HANDLING

Fresh capillary specimen

EQUIPMENT AND MATERIALS

Equipment:
Abbott® Point of Care i-STAT Analyzer

Materials:
Abbott® Point of Care i-STAT PT Control

REAGENTS- PREPARATION and STORAGE

1. Abbott® Point of Care i-STAT PT Control, Level 1 (Normal) lyophilized preparation of human normal plasma.
2. Dade® Ci-Trol Coagulation Control Level 2 (Abnormal) lyophilized preparations of human abnormal plasma.

- Prior to testing, controls and reconstituting fluid should stand at room temperature (18-30º C) for at least 45 minutes.
- Reconstitute one vial at a time. Control solution must be used immediately (less than 30 seconds) after reconstitution and mixing.

1. After 45 minute warm up time, remove stopper from both the control and reconstituting fluid vials.
2. Pour entire contents of reconstituting fluid (CaCl) vial into the lyophilized control vial. Replace the stopper on the control vial.
3. Allow the vial to stand at room temperature for 1 minute.
4. Mix contents by swirling gently for 1 minute, then inverting for 30 seconds.

Note: To minimize foaming, avoid vigorous or rapid mixing. Visually inspect for full reconstitution of lyophilized control material.

5. Using a plastic pipette, immediately transfer the control solution from the vial into the PT/INR cartridge.
6. Immediately seal the cartridge and insert into i-STAT analyzer.

Note: Additional testing of the same vial of control may be performed if solution is used within 30 seconds of reconstitution.

Stability after reconstitution: Must be used immediately (within 30 seconds) after reconstitution and mixing.

- Cartridges in sealed pouches are stable through the expiration date when stored at 2 – 8º C and two weeks at room temperature (18-30º C)
- The box of cartridges should equilibrate to room temperature (18-30º C) for at least one hour prior to use. Individual cartridges require five minutes to equilibrate. Once opened use immediately.

CALIBRATION - None. See "Electronic Stimulator Testing."

QUALITY CONTROL

1. Controls should be tested at initiation of testing, with each new lot/shipment and at least weekly. This test will only be performed between 10 a.m. and 4 p.m. and will require only one set of controls.
2. Controls should be run in the same manner as the patient samples.
3. Consult the Abbott® website or Technical Support for a copy of Value Assignment Sheet. The Value Assignment Sheet displays target values and expected ranges for properly functioning

equipment and controls.
4. Performance characteristics of the i-STAT PT/INR measurement have not been established for INRs above 6.0

5. Verified Clinical range = 0.9- 6.0 INR. Verified Reportable range = 0.9 – 8.0 INR.
6. Corrective action when tolerance limits are exceeded
   - Refer to System Manual
   - Rerun out of range control material if within 30 seconds of reconstitution. Otherwise, reconstitute a new vial of control
   - Verify cartridge performance, check lot number.
   - Check instrument performance, check software version.
   - Document any actions taken to identify and correct the problem before reporting any patient results

PROCEDURE

CAUTION: The i-STAT PT/INR cartridge is designed to accept a sample size between 20 µl and 45 µl. A single drop of blood from either a figure puncture or as formed at the tip of a needle will typically be in this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled.

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled (refer to Capillary Puncture procedure). Allow finger to dry thoroughly before sampling.
4. Remove cartridge from pouch. Handle cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
5. Press ON/OFF key to turn analyzer on. Press 2, i-STAT cartridge from Test Menu.
6. Prick the finger with the lancet device as indicated by Capillary Procedure.
7. Gently squeeze the finger, developing a hanging drop of blood. **DO NOT WIPE** this drop; use the first drop of blood for your sample. This part of the procedure is different than the Capillary Procedure. For this test ONLY, you do not want to wipe off the first drop.
8. Avoid repetitive pressure (milking) as it may cause hemolysis or tissue fluid contamination.
9. Touch the drop of blood against the bottom of the cartridge sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
10. Apply sample to ensure the sample reaches the fill mark indicated on the cartridge.
11. Fold the sample closure over the sample well and press the rounded end of the closure until it snaps into place.
12. Scan or enter the operators ID. Scan or enter specimen accession number. Repeat.
13. View results on display and print.
14. Remove cartridge after “Cartridge Locked” message disappears and discard.

NOTE: To simplify putting the sample into the test cartridge, bring the sample cartridge up to the finger. Ensure the iSTAT analyzer remains on a flat vibration-free surface during testing.

PROCEDURE NOTES

1. On a daily basis, the performance of the i-STAT analyzer should be verified with the Electronic Simulator Test at least once every eight hours.
2. On receipt of new cartridges, verify transit temperature was satisfactory utilizing the temperature strip included with the shipment. For each shipment or lot change, analyze Abbott® Point of Care iSTAT PT Control Level 1-Normal and Abbott® Point of Care iSTAT PT Level 2 – Abnormal to assure proper temperature was maintained during shipment and cartridge performance.
3. I-STAT analyzer must remain on a level, vibration free surface for testing.

REPORTING RESULTS

The PT/INR is reported as an INR or International Normalized Ratio and, optionally, by seconds. The INR is the recommended method of result reporting for monitoring of oral anticoagulant therapy. The reported time in seconds is derived from the PT/INR result and an equation utilizing an ISI of 1.05 and a Mean Normal Plasma PT time of 12.0 seconds. Record values in the computer system. Record quality control values on the proper worksheet and computer system.

- Lipemic, or icteric samples must be noted with the result.
- If results appear inconsistent with the clinical assessment, the patient sample should be recollected and retested with another cartridge.
- If the coagulation time cannot be obtained due to an analysis error, ***, refer to page 12 "Abbott i-STAT Test Flags"" and "Quality Check Messages and Codes" in the User's Guide.
- Do not report out ">secs" for a NO COAGULATION error. Obtain a second capillary specimen using a different finger. If the iSTAT reports out ">secs" a second time contact the Anti-Coagulation Clinic for further instructions.
- INR results that are >8.0 are reported at >8.0

REFERENCE RANGE: 2.0-3.5 seconds

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ALERT VALUES: 5.0 seconds

Alert results need to be repeated with a second capillary collection using a different finger. INR values greater than 5.0 seconds must be called to the Anticoagulation Clinic or provider.

LIMITATIONS OF THE PROCEDURE

1. Oral anticoagulants depress the production of factors II, VII, IX and X in the liver by inhibiting the action of Vitamin K. The PT is sensitive to the levels of factor II, VII and X and is used to monitor patient therapy with oral anticoagulants.
2. Many commonly administered drugs may affect the PT results. These should be considered when unusual or unexpected abnormal results are obtained. Unexpected abnormal results should be followed by further coagulation studies to determine the source of the abnormality.
3. Poor technique in sample collection may compromise the results.
4. Glass syringes or tubes prematurely activate coagulation, resulting in accelerated clotting times and lower INR results.

5. Abbott Point of Care has not characterized the i-STAT PT/INR test with patients that have lupus anticoagulant antibodies. If the presence of lupus antibodies is known or suspected, consider using inattentive prothrombin time method.
6. The i-STAT PT/INR test is not affected by fibrinogen concentration between 70 -541 mg/dl.
7. The i-STAT PT/INR test is not affected by unfractionated heparin concentrations up to 1.0 U/ml.
8. Hematocrits in the range of 24-54% PCV have been demonstrated NOT to affect results.
9. Cubicin (daptomycin for injection), has been found to cause false prolongation of PT and elevation of the INR when using i-STAT PT/INR test. An alternate method of testing is recommended.

REFERENCES

1. National Committee for Clinical Laboratory Standards. Collection, transport and processing of blood specimens for coagulation testing and performance of coagulation assays. 2nd Edition. Approved Guideline. NCCLS Publication H21-A2. Villanova, PA, 1991.
2. National Committee for Clinical Laboratory Standards. One-stage prothrombin time test (PT) and activated partial thromboplastin time test (APTT). Approved Guideline. NCCLS Publication H47-A. Villanova, PA, 1995.
3. Abbott® Point of Care i-STAT User's Guide, Art.714254-00E, 7/18/06.
4. Abbott® Point of Care i-STAT Waived Testing and Regulatory Guide, Art. 720-755-00A, 2007.
5. Abbott® Point of Care i-STAT Control Enclosure, Art.722744-01A, 10/14/2008.
6. Abbott® Point of Care i-STAT Prothrombin Time (PT/INR) Procedure, Art. 715236-00K, 2/23/09.
7. Adcock DM, Kressin DC, Marlar RA. Are Discard Tubes Necessary in Coagulation Studies? Lab Med 1997:28:530-533
8. Yawn BP, Loge C, Dale J. Prothrombin Time. One Tube or Two. AmJ Clin Path 1996:794-797
9. Gottfried EL, Adachi MM. Prothrombin Time and Activated Partial Thromboplastin Time can be performed on the First Tube. Am J Clin Path. 1997:107:681-683
10. Adcock DM, Kressin DC, Marlar RA. The Effect of Time and Temperature Variables on Routine Coagulation Testing. Accepted. Bloof Coagulation and Fibrinlysis
11. CLSI. How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline--Second Edition, CLSI Document C28-A2 (ISBN 1-56238-406-6, CLSI 940 West Valley Road, Suite 1400, Wayne, PA 19087 USA, 2000.

KAISER PERMANENTE®

Clinical Pharmacy Anticoagulation Service (CPAS) POC INR Guidelines	Policy ID #: N/A Issued: Effective: February 2010 Last Reviewed: February 18, 2010 Last Revised: February 18, 2010
Department: **Clinical Pharmacy Anticoagulation Service (CPAS)**	
Accountable Position: **Sr. Manager, Clinical Pharmacy Services**	
Target Audience: **CPAS Clinical Pharmacy staff, clinical practitioners**	
P & P Intent: **Establish a consistent and thorough process for selecting appropriate patients who will use the Point of Care (POC) device for INR results**	
Settings for Application: **CPAS**	Pages: **2**

Policy Statement

The purpose of this guideline is to provide a process for the use of a point of care (POC) device to perform INR tests at the Westminster lab in the Kaiser Permanente Colorado Region. This process will describe the use and guidelines for POC testing.

Procedures

I. Location:
- A. The POC device will be located at the Westminster Medical Office laboratory.
- B. The POC device and test strips will be stored and maintained by laboratory personnel at the above location. Refer to the specific laboratory protocol for storage and maintenance.

II. Guidelines for Use:
- A. INR testing using the POC device will be limited to patients who meet the following criteria:
  - i. Venipuncture is not possible due to limited venous access.
  - ii. Patients who have been determined as appropriate candidates for POC testing by the Clinical Pharmacy Anticoagulation Service.
- B. INR testing will occur on Monday through Friday each week between the hours of 10:00am to 4:00pm.
- C. Patients receiving parenteral anticoagulation with fondaparinux, unfractionated heparin, or low-molecular-weight heparin should have INR testing by venipuncture whenever possible. If POC testing must be used, it should occur immediately prior to the next scheduled dose of parenteral anticoagulant to avoid interference of these agents with INR results. If an "Error" message is encountered on the POC device, the patient should be tested using venipuncture.
- D. CPAS will contact the Westminster lab (303-457-6552) with appropriate patient information for the initial POC INR test. Orders must be placed in Health Connect by CPAS Staff for all INR tests.
- E. Patients who are eligible for POC testing should use the same method of testing routinely to decrease variability in results.
- F. INR values will be manually entered in to the lab system by lab personnel (protime values are not needed).
- G. INR 5.0 or greater must be phoned to the Anticoagulation Clinic or pharmacist.
- H. Hematocrit ranges between 24-54% will not affect test results. If a reading is obtained on a patient whose hematocrit is outside this range the result cannot be considered as accurate.

III. Review/Revision of policy:

A. This policy shall be reviewed at least yearly.