

**DEPMEDS LABORATORY PROCEDURES  
DEPARTMENT OF CLINICAL SUPPORT SERVICES  
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL  
FORT SAM HOUSTON, TEXAS 78234-6137**

MCCS-HCL

08 Oct 02

**STANDING OPERATING PROCEDURE**

**Rapid Point Coagulation Procedure  
Prothrombin Time (PT), Activated Partial Thromboplastin Time (aPTT)**

**I. PRINCIPLE:**

A. The determination of the citrated whole blood or citrated plasma prothrombin time (PT) utilizes the RAPIDPOINT COAG analyzer and the appropriate RAPIDPOINT COAG PT test card. The PT test card reagent consists of thromboplastin extracted from human placenta, CaCl (10 mM), Paramagnetic Iron Oxide Particles (PIOP), buffers and stabilizers. The subsequent clot formation from the reaction of the sample with tissue thromboplastin and calcium in a pre-warmed card is interpreted as the endpoint of the reaction by the RAPIDPOINT COAG analyzer. The PT assay is sensitive to deficiencies in the extrinsic pathway, including factor VII, and common pathway factors, V, X, II (prothrombin) and I (fibrinogen). The PT assay also is sensitive to the effect of Vitamin K antagonists like Warfarin and Coumadin on clotting.

1. The PT assay can be used to monitor the effect of oral anticoagulant therapy.
2. The RAPIDPOINT COAG is particularly useful for the bedside determination of the PT in the monitoring and management of oral anticoagulant therapy in the hospital, clinic or home health care setting because it reduces the time to obtain results.

B. The determination of the citrated whole blood or citrated plasma activated partial thromboplastin time (aPTT) utilizes the RAPIDPOINT COAG analyzer (Cardiovascular Diagnostics, Inc.) and the RAPIDPOINT COAG aPTT test card (Cardiovascular Diagnostics, Inc.). The aPTT consists of the recalcification of plasma, using CaCl<sub>2</sub>, in the presence of phospholipid (dried rabbit brain, 12.5 mmol/L) and the particulate activator aluminum magnesium silicate, with the subsequent endpoint interpreted as clot formation by the RAPIDPOINT COAG analyzer. The aPTT assay is sensitive to deficiencies in intrinsic pathway factors VIII, IX, XI, XII, prekallikrein, and high molecular weight kininogen and common pathway factors, V, X, II (prothrombin) and I (fibrinogen).

1. The aPTT assay also is sensitive to the presence of unfractionated heparin and can be used to monitor the effects of heparin on clotting.

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2. The RAPIDPOINT COAG is particularly useful for the bedside determination of the aPTT in the monitoring and management of heparin therapy in the intensive care units because it reduces the time to obtain results.

**II. SPECIMEN:**

- A. Type – Citrated whole blood or plasma. Specimen of choice citrated plasma.
- B. Volume, optimal/minimum – 3 mls/0.03ml.
- C. Collection container – Light Blue Top coagulation tubes are filled with buffered sodium citrate solution. Citrate concentrations of either 0.109 mol/l (3.2 %) or 0.129 mol/l (3.8 %) are available. The choice of the concentration depends upon the policies of the laboratory. The mixing ratio is 1 part citrate solution to 9 parts blood.
- D. Stability/Storage – Citrated whole blood should be tested or processed to plasma within 15 minutes of collection. Plasma samples should be run within 2 hours of collection.
- E. Unacceptable specimens – specimens collected in inappropriate collection tubes, clotted specimens or citrated whole blood specimens received 15 minutes after collection.

**III. REAGENTS/SUPPLIES/EQUIPMENT:**

A. Reagents:

1. Reagent List:

Reagent	Cat #	NSN
PT 1.0 Test Cards	118570	6550-01-492-1502
PT 1.0 Test Cards	118564	6550-01-492-1503
aPTT Test Cards	118590	6550-01-492-1500

2. Reagent Preparation – No special preparation required except to warm the individual test pouch to room temperature before removing the card from the pouch. Test card must be used within 15 minutes after the pouch is opened.
3. Storage Requirements - Store Rapidpoint Coag test cards at 2 to 8°C (36 to 46°F).

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Reagent	Storage	Stability
Test Cards (Closed pouch)	2-8°C	Until stated expiration
Test Cards (Closed pouch)	20-25°C	Two Week
Test Cards (Open pouch)	20-25°C	15 minutes

4. Performance Parameters - Test cards will retain viability under the following conditions:
- While sealed in its pouch and stored properly, the test card is usable until the expiration date embossed on its foil pouch.
  - After warming to RT, a test card in an unopened pouch is usable for 2 weeks.
  - After warming to RT, a test card in an opened pouch must be used within 15 minutes.

**Note:** Do not repeatedly warm RapidPoint Coag test cards and return them to the refrigerator.

B. Supplies and Equipment:

1. Supply and Equipment List:

Component	Cat #	NSN
Rapidpoint Coag Analyzer	118608	6515-01-492-0051
Power Supply	118615	6630-01-491-9777
Epson Printer Interface Cable	119955	6550-01-492-1544
Epson Printer	120655	6550-01-492-1537
Epson Printer Power Supply	120657	6550-01-492-1534
Epson Printer Paper	120656	6630-01-492-3638

2. Operating environment for coagulation analyzer:
- Operate the analyzer on a stable, level surface in an area where the ambient RT is between 18 and 32°C (65 and 90°F).
    - Do not immerse the instrument in water or other liquids.
    - Do not operate in an explosive atmosphere.
    - Equipment does generate, uses, and can radiate radio frequency energy. If not installed IAW the operator's manual it can cause harmful interference to radio communications.

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- b. Set up – Refer to Rapidpoint Coag Operator’s Manual, Section 3 @ [www.armymedicine.army.mil/jrcab/OpManRapidpt.pdf](http://www.armymedicine.army.mil/jrcab/OpManRapidpt.pdf)

**IV. Calibration:** The only calibration required by the operator is to set the date and time as required. When the analyzer is turned on, it automatically performs a series of self-tests to verify hardware integrity. If an instrument Self-Test fails, an error message is displayed. Consult the Section 7 of the Operator’s manual.

**V. Quality Control:**

A. Quality Control Materials:

QC Material	Cat #	NSN
Rapid QC PT Lvl 1	118576	6550-01-492-0479
Rapid QC PT Lvl 2	119151	6550-01-492-0492
Rapid QC aPTT Lvl 1	118595	6550-01-492-0585
Rapid QC aPTT Lvl 2	119153	6550-01-492-0592
Electronic QC (EQC)	121907	6550-01-492-1499

- B. QC Material Preparation – **Note:** Do not reconstitute the control plasma until the test card has been warmed in the analyzer.
1. Hold the vial in the protective sleeve and firmly bend the vial over the edge of a tabletop until the inner glass ampule is completely crushed.
  2. Remove the vial from the sleeve and shake vigorously until no lumps of lyophilized plasma are visible (about 20 times).
  3. Immediately dispense five (5) waste drops of reconstituted plasma into a biohazard waste container to clear the vial filter.
  4. When prompted, add one drop of reconstituted plasma into the sample well (colored circle) on the test card.
- C. Storage Requirements -

Reagent	Storage	Stability
QC Controls	2-8°C	Until stated expiration
QC Controls (Unreconstituted)	20-25°C	Two Weeks
QC Controls	Reconstituted	5 Minutes
EQC	20-25°C	6 Months after date of first use.

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## D. Performance Parameters:

1. Precision studies of the PT controls with the PT test card show an interlaboratory variation resulting in a coefficient of variation (CV) of:
  - a. 3% - 6% for the PT level 1 control.
  - b. 5% - 10% for the PT level 2 control.
2. Precision studies of the aPTT controls with the aPTT test cards show an interlaboratory variation resulting in a CV of 8% for aPTT controls.

## E. Daily QC:

1. Perform analyzer self-test.
2. Analyze EQC
  - a. At ready screen, swipe the EQC card.
  - b. Insert card into the analyzer cardholder when instructed to do so.
  - c. When the card is properly warmed, the EQC test automatically begins. Test in progress is displayed on screen.
  - d. At the end of the test, Result 1 clotting time (CT) and signal strength (Signal) are displayed. CT result represents the clotting time returned by the algorithm analyzing the AC signal collected from the EQC card.
  - e. Press ENTER to obtain Result 2. At the end of the second test, Result 2 CT and Signal are displayed.
  - f. Press ENTER to continue testing and obtain Result 3, CT and Signal.
  - g. Press ENTER, if the tests pass, a message is displayed "EQC TEST, TEST PASSED, please remove card."
  - h. If the EQC TEST FAIL message appears during any of the three levels, press any key as indicated. Remove the EQC test card when instructed to do so.
    - (1) Repeat the test.
    - (2) If results continue to fail out of range, contact the OIC/NCOIC to resolve the problem or contact the technical representative.
3. Record results on QC Log.
4. Before running patient samples run QC Level I and Level II for each card type and record results.
  - a. Quality Control Procedure: After bringing all materials to correct operating temperature.

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<b>Step</b>	<b>Action</b>
1	Swipe test card and insert, select QC option
2	Break ampule and mix vigorously 20 times
3	Discard 5 drops
4	Apply one drop to sample well
5	Record result

F. Card Lot # change (**Notify OIC/NCOIC**):

1. Verify/establish new patient normal value/range for each card type.
2. Verify/establish new QC ranges.

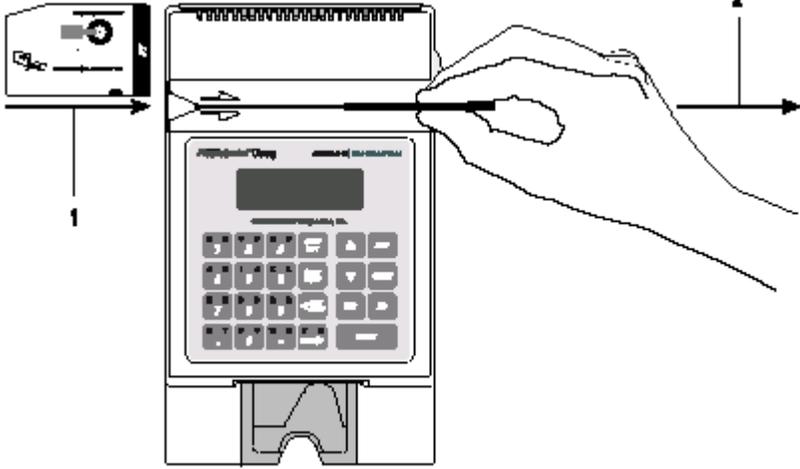
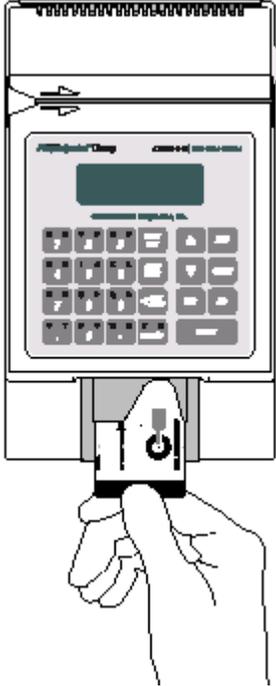
G. QC Lot # change (**Notify OIC/NCOIC**):

1. Establish new QC ranges.
2. Enter new QC ranges into Rapidpoint.

**VI. Patient Procedure:** Perform the following steps to analyze a specimen:

<b>Step</b>	<b>Action</b>
1	Bring supplies to correct operating temperatures.
2	Run/check QC to ensure instrument and materials are operating IAW manufactures guidelines.
3	Remove the test card from its pouch.
4	Hold the test card face-forward, with magnetic stripe toward the back of the analyzer.

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5	<p>Pass the card at a steady rate from left to right through the card reader.</p>  <p>1 Pass through reader slot in this direction. 2 Pull card through reader slot in this direction.</p>
6	<p>Insert card when prompted.</p> 
7	<p>Select sample type and press ENTER.</p> <ul style="list-style-type: none"><li>• Citrated Plasma</li><li>• Citrated Whole Blood</li><li>• Control plasma</li><li>• Non-Citrated Whole Blood</li></ul>

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7	Enter specimen accession number or select control level if analyzing a control sample. <ul style="list-style-type: none"> <li>When performing the second test on same patient, press ↑ to bring up previous accession number</li> </ul>
8	Mix sample several times
9	Add a sample drop to the well on the test card when prompted. <div style="text-align: center;">  </div>
10	Remove the test card when prompted.
11	Verify that a sufficient amount of sample was added to the card. <ul style="list-style-type: none"> <li>Entire gray area should be covered by sample</li> </ul>
12	Follow instrument prompts <ul style="list-style-type: none"> <li>On PT cards select “YES” for INR calculation</li> </ul>
13	Enter patient results in appropriate patient logs or LIS/HIS.

**VII. Calculations:** None

**VIII. Results:**

A. Analyzer will compare result to established ranges. If outside the reference range, the analyzer will indicate, “Result out of Range”.

B. Reference Range:

PT	11.8 – 14.1 seconds
APTT	22.1 – 33.7 seconds
INR	Routine Therapy 2.0 - 3.0

C. Critical Values:

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PT	>17 seconds
PT (on coumadin)	>30 Seconds
APTT	>40 seconds

**IX. Procedural Notes:** For all critical values, repeat the test(s) and contact the provider. Annotate the time/date and name of who was contacted.

**X. References:**

- A. Bayer, Rapid Point Operator's manual, 1999
- B. PT Test Cards package insert, Bayer Inc, Feb 00
- C. APTT Test Cards package insert, Bayer Inc, Mar 00
- D. PT NC Test Cards package insert, Bayer Inc, Mar 00
- E. EQC package insert, Bayer Inc, Aug 99
- F. Fritsma, GA: Laboratory Evaluation of Hemorrhage and Thrombosis. *In* Rodak, BF (ed): Diagnostic Hematology. Philadelphia; W.B. Saunders Company, 1995:562-567.