UnityPoint Health Pekin
Department of Pathology
Pekin, IL 61554

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ACTIVATED PARTIAL THROMBOPLASTIN TIME

Sta Compact Max

I. PRINCIPLE

The activated partial thromboplastin time (APTT) is a general coagulation screening test of the coagulation factors XII, XI, IX, and VIII, X, V, II and fibrinogen.

II. CLINICAL SIGNIFICANCE

A prolongation of the APTT is encountered in the following situations:

A. Congenital Deficiencies
   1. If the prothrombin time (PT) is normal, the following factors may be deficient: factor VII, IX, XI, XII.
   2. If all these factors are normal, a deficiency in the following should be considered: prekallikrein (Fletcher factor) or HMW kininogen (Fitzgerald factor).

B. Acquired Deficiencies and Abnormal Conditions
   1. Liver diseases
   2. Consumptive coagulopathy
   3. Fibrinolysis
   4. Circulating anticoagulants (LA type or circulating anticoagulant against a factor)
   5. During heparin or oral anticoagulant therapy
   6. Treatments with thrombin inhibitors (e.g., hirudin, argatroban).

III. SPECIMEN

A. 2.7 ml or 1.8 ml Blue Top Tube. Mix nine parts of freshly collected blood with one part of 0.11 mol/L (3.2%) sodium citrate anticoagulant. Invert the tube gently three or four times immediately after venipuncture to ensure proper mixing of blood an anticoagulant.
   - If blood is drawn from an indwelling catheter, the line should be flushed with 5.0 mL saline and the first 5 mL of blood or six dead space volumes of the catheter discarded.

B. The citrate concentration must be adjusted in patients who have hematocrit values above 55%. See STA Compact Max Start Up Operating Procedure.

C. Specimens that are clotted, collected in the wrong tube, have visible hemolysis or have less than a 90% fill or >10% overfill are rejected.

D. It is unacceptable to combine the contents from separate under-filled sodium citrate tubes.

E. Handling/ Storage Conditions:
   1. The whole blood specimen is checked for clot formation by gently inversion and observation.
   2. Centrifuge the capped blood specimen as soon as possible after collection for 2 minutes at 7200 RPM (3500 x g) in the Stat Spin Express 3 or S/P® Brand Stat-60.
      a. Testing requires produce platelet-poor plasma (platelet count $<10x10^9$/L).
      b. The plasma may remain on the packed cells if testing immediately or separated if freezing.

c. To separate plasma, use a plastic transfer pipette; remove the plasma to a polypropylene/ plastic tube until ready to test.

3. If testing is not complete within acceptable time for specimen stability (see below), the plasma must be removed to a polypropylene/ plastic tube and frozen. A frost-free freezer should not be used. Frozen plasma samples must be rapidly thawed at 37°C while gently mixing and tested immediately after thawing.
4. If testing is delayed, the sample may be held for 4 hours at room temperature.
5. Specimens should be stored on board the analyzer or at room temperature after testing. Once removed from the analyzer, caps must be removed if additional testing is ordered.

IV. REAGENTS

A. STA® - PTT A 5 reagent containing cephalin prepared from rabbit cerebral tissues and a particulate activator (silica) in a buffered medium, lyophilized.

1. Preparation: Reconstitute each vial with 5 ml of fresh reagent grade Nerl water. Allow the reconstituted material to stand at room temperature (18-25 °C) for 30 minutes. **Mix vigorously** by turning the vial upside down 5-10 times or vortex to obtain a homogeneous solution and install the perforated plastic cap on the vial.
2. Storage: The reagent in intact vials is stable until the expiration date indicated on the box label, when stored at 2-8 °C.
   Once reconstituted, the reagent is stable:
   - 24 hours on STA Compact® with the perforated cap in place
   - 7 days at 2-8 °C in its original capped vial.

   Do not freeze the reagent.

B. STA® - $CaCl_2$ 0.025 M 0.025 M $CaCl_2$ solution.

1. Solution Preparation: If the solution is refrigerated, allow it to stand at room temperature (18-25 °C) for 30 minutes, before use.
2. Solution Storage: The solution in intact bottles is stable until the expiration date indicated on the box label, when stored at 2-25 °C.
   After opening, it remains stable for:
   - 3 days on and STA Compact®

C. STA® - Coag Control N + ABN Plus kit: provides a normal plasma and an abnormal plasma intended for the quality control of the following tests on analyzers of the STA® brand name suitable with these reagents: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen.

1. Preparation: Reconstitute each vial of Reagent 1 or 2 with exactly 2 ml of fresh reagent grade Nerl water. Allow the reconstituted material to stand at room temperature (18-25 °C) for 30 minutes. Then, swirl the vial gently before use.
2. Storage: The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C. Once reconstituted, Reagents 1 and 2 remain stable for 24 hours.

D. STA – DESORB U is a decontaminating solution for use with the STA Compact® It is designed as an integral part of the STA® analyzer system.

1. Preparation: Install a new STA® - maxi Reducer) and the perforated cap on a freshly opened bottle of STA® - Desorb U before loading it into the analyzer.
   N.B.: a fine white sediment may be observed in the bottom of the bottle; this has no effect on the performance of the product.
   On STA Compact® model, place one bottle in the product drawer.
2. Storage: The reagent in intact bottles is stable until the expiration date indicated on the box label, when stored at 2-8 °C and protected from light.
   Once opened, the STA® - Desorb U with STA® - maxi Reducer and perforated cap in place, is stable for 5 days on board STA Compact®
   The STA® - Desorb U reagent contains KOH, a corrosive chemical at the concentration provided (< 1 %).
   Danger:
   a. Causes severe skin burns and eye damage.
   b. Wear protective gloves/protective clothing/eye protection/face protection.
   c. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
   d. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

V. INSTRUMENTATION/EQUIPMENT

A. STA Compact®
B. Cuvette roll – 1000 (REF 38669)
C. NERL or Distilled Water
D. Pipettes & tips

VI. CALIBRATION

No calibration of the system in necessary for performing an APTT if the results are reported in seconds.

VII. QUALITY CONTROL

A. It is necessary to run controls in order to ensure accuracy and reproducibility of the results. Two different levels of control should be used.
B. Daily QC Schedule for the N and Abn Plus controls: Check product status→After morning run, perform daily maintenance.
   1. Quality control for PT and APTT is automatically run when the STA Compact Max® has to perform an analysis using that methodology and when the time since the last control exceeds 8 hours. The time period is defined in the METHODOLOGIES screens
   2. 09:00- 09:30 Make up new QC and any reagents needed
   3. 09:30-10:00 Load QC material and Manually run QC
      a. Reconstituted Coag Control Plus N+ABN is stable onboard the Sta Compact Max for 24 hours
   4. 17:30-18:00 Manually run QC if sample are not being run
   5. 01:30-02:00 Manually run QC if sample are not being run
   6. QC will automatically run when testing switches to a new vial of reagent.

C. If Quality Control is not within acceptable range, check that all the components of the test system are functioning correctly, i.e., reagents, assay conditions, etc. If necessary, repeat the tests.
D. See STA Compact Max Start Up Operating Procedure or Reference Manual for further information.

VIII. PROCEDURE:

A. Refer to STA Compact Max Start Up Operating Procedure for the analyzer before running patient and QC specimens at the start of each shift.
B. There are two modes to load samples.
   1. Automatic Mode:
      a. Instrument is connected to a LIS and can download testing
      b. Load sample onto instrument and the tests will auto-populate with test ordered in LIS
   2. Manual Mode used for LIS downtime or Interface downtime:
      a. Instrument is either not linked to a LIS, or sample is not ordered in the LIS
      b. Load sample onto instrument, then select the test(s) to be performed

IX. REPORTING RESULTS

Report results using interface/manual result entry in the LIS system.
Reference interval for UPH-Pekin for APTT's: 23.7 - 34.7 seconds.

A. Procedure for Abnormal Results:
   1. Critical Value: APTT's ≥ 127 seconds

   2. Analytical Measurement Range: 10 - 220 seconds
      a. Below AMR turn out as <10 seconds
      b. Above AMR turn out as >220 seconds

X. LIMITATIONS OF THE PROCEDURE

A. When monitoring heparin therapy, any release of platelet factor 4 (PF4) which is a potent inhibitor of heparin, represents a major source of error. Do not collect blood in glass, which might cause this release; collect blood in plastic, siliconized glass or CTAD tubes.
B. Perform centrifugation within 1 hour after sample collection if the blood was collected in conventional citrate anticoagulant.

XI. REFERENCES

A. STA Compact Max® Reference Manual June 2016.
B. STA Compact Max® User Guide November 2015.
C. STA Compact Max® Software version 106.08.01.00

POLICY CREATION :	Date
Author: Kelly Hall, MT (ASCP)	08/23/18
Medical Director: Kathryn O. Kramer, M.D.	08/23/18

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
8-24-18	Kathryn O. Kramer	
SECTION MEDICAL DIRECTOR		
	N/A	

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date