Methodist Health Services Corporation &
UnityPoint Health Methodist
Department of Pathology
Peoria, IL 61636

Effective February 6, 2017
Revised: April 11, 2017

APTT
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 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. Type:

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. A syringe or evacuated tubes (blue top) may be used with caution for collection. If multiple specimens are collected, the coagulation sample should be the second or third tube collected. 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 or used for other laboratory tests. The citrate concentration must be adjusted in patients who have hematocrit values above 55%. Specimens that are clotted, collected in the wrong tube, have visible hemolysis or have less than a 90% fill should be rejected.

B. Handling/ Storage Conditions:

The whole blood specimen is checked for clot formation by gentle inversion and observation. Centrifuge the capped blood specimen as soon as possible after collection for 5 Min at 4000RPM or at a speed and time required to produce platelet poor plasma (platelet count $<10x10^9/L$). The plasma may remain on the packed cells if testing immediately or separated if freezing. To separate plasma, use a plastic transfer pipette; remove the plasma to a

polypropylene/plastic tube until ready to test. If testing is not complete within 24 hours, 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. If testing is delayed, the sample may be held for 44 hours at room temperature. 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 (2) 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:
   24 hours at 37 °C
   3 days on and STA Compact®

C. **STA® - Coag Control N + ABN** 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 1 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 8 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:

- **Causes severe skin burns and eye damage.**
- **Wear protective gloves/protective clothing/eye protection/face protection.**
- **IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.**
- **IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**

V. INSTRUMENTATION/EQUIPMENT

STA-R®, STA Compact® or STA Satellite®
Cuvette roll – 1000 (REF 38669) or Satellite cuvette roll (REF 39430)
Centrifuge
Distilled Water
Pipettes & tips

VI. CALIBRATION

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

VII. QUALITY CONTROL

STA®- Coag Control N + Abn. It is necessary to run controls in order to ensure accuracy and reproducibility of the results. Two different levels of control should be used. Prepare the control reagents and scan the information contained in the barcode printed on their respective Assay Value insert to the instrument.

VIII. PROCEDURE:

Refer to START-UP/Operating procedure for the analyzer before running patient and QC specimens at the start of each shift.

IX. REPORTING RESULTS

Report results using interface/manual result entry in the LIS system.
Reference interval for UPH-Methodist for APTT"s: 22.6-34.1 seconds.

A. **Procedure for Abnormal Results:**

1. **Critical Value**: APTT's ≥ 127 seconds
   Refer to the critical values policy for how to handle critical values.

2. **Analytical Measurement Range**: 20-220 seconds
   Results below 20 seconds should be turned out as <20 and those above 220 seconds as >220. Results that are outside of the validation range (>max <min) and have a blue flag will need to be "confirmed" on the analyzer. These do not cross into the LIS system until validated in coag expert.

   To validate the result in coag expert;
   coag expert→workstation→dashboard→uncheck everything except "to be validated"→double click on the patient→click the validation mode button in the upper right corner→click in the box to the left of the result that needs to be validated→save.

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 and within 4 hours if the blood was collected with CTAD tubes.

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

MMCI Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

POLICY CREATION :		
Author:	***Kim Paige, CLT***	***December 20, 2016***
Medical Director:		***January 29, 2017***
Elizabeth A. Bauer Marsh, MD	Elizabeth A. Bauer Marsh, M.D.	

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
January 29, 2017	Elizabeth A. Bauer-Marsh	Elizabeth A. Bauer-Marsh MD
SECTION MEDICAL DIRECTOR		
January 29, 2017	Julia Adams, MD	Julia Adams, M.D.

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
0	Initial Release	Kim Paige	1/24/17
1	Corrected critical value range and specimen stability misprint and centrifuge time.	Kim Paige	3/1/17

Reviewed by

Lead	Date	Coordinator	Date	Asst. Manager	Date	Medical Director	Date
Kim Paige	1/17/17	Jane Bambenek	1/20/17	Kathy L. Turpin	1/17/17	Julia Adams, M.D.	1/20/17
Kim Paige	3/1/17	Jane Bambenek	3/1/17			Julia Adams, M.D.	4/11/17