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

Effective: January 29, 2017
Revised: April 11, 2017

Fibrinogen
Sta Compact Max

I. PRINCIPLE

The **STA® - Fibrinogen** 5 kit is intended for the quantitative determination of fibrinogen levels in plasma by the clotting method of Clauss. In the presence of an excess of thrombin, the clotting time of a diluted plasma has a direct bearing on the level of plasma fibrinogen. The chronometry measurement principle consists in measuring changes in the oscillation amplitude of the ball inside the cuvette, using inductive sensors.

II. CLINICAL SIGNIFICANCE

An increase of fibrinogen level is found in cases of diabetes, inflammatory syndromes, and obesity. A decrease of the fibrinogen level is observed in DIC and fibrinogenolysis. Furthermore, fibrinogen seems to be involved in the pathogenicity of thrombotic cardiovascular events.

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 4 Min at 4000RPM or at a speed and time required to produce platelet-poor plasma (platelet count <10x109/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® - Fibrinogen 5** (REF 00674): lyophilized titrated human calcium thrombin (approx. 80 NIH units/ml) containing a specific heparin inhibitor to allow the assay of fibrinogen in heparinized plasma samples.

1. **Preparation:** Reconstitute each vial of STA®- Fibrinogen 5 with 5 ml of reagent grade Nerl water. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Swirl vial gently. Then place the perforated plastic cap on the vial.
2. **Storage:** The reagent in intact vial is stable until the expiration date indicated on the box label, when stored at 2-8 °C.
   Once reconstituted, the reagent is stable:
   a. 5 days with the perforated plastic cap in place on STA Compact®
   b. 14 days at 2-8 °C in its original capped vial.

B. **STA® - Owren-Koller** (REF 00360) is a buffer solution intended for use as a diluent for reagents and patient samples in coagulation tests.
STA® - Owren-Koller: buffered solution* of pH approximately 7.35.

1. **Preparation:** Allow the reagent to stand at room temperature (18-25 °C) for 30 minutes before use. Do not install either an STA® - Reducer or a perforated cap on the buffer bottle if the solution is to be used on analyzers of the STA® line.
2. **Storage:** The buffer solution in intact bottles is stable until the expiration date indicated on the box label, when stored at 2-8 °C.
   After opening, it remains stable for:
   a. 3 days on STA Compact®
   b. It has been determined that we will change the buffer every 24 hours. Please aliquot the buffer into a 5ml (12 x 75) glass tube when putting on the analyzer. Label glass tube with reagent name, date and time you put it on the analyzer. Refrigerate the rest of the buffer for stability purposes.

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.
   a. 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.**

CAUTION:

1. Store reagent kit at 2-8 °C.
2. For in vitro diagnostic use only.

V. INSTRUMENTATION/EQUIPMENT

STA-R®, STA Compact® or STA Satellite®
Cuvette roll – 1000
Centrifuge
Distilled Water
Pipettes & tips

VI. CALIBRATION

The pre-calibrated fibrinogen values are identical for all the vials of each lot.
The pre-calibration has been determined with a secondary standard of the 09/264 International Standard established in 2011. To enter the calibration data on the analyzer, scan the barcode printed on the Assay Value insert across the instrument barcode reader. The calibration data will be validated for the lot being used once the two fibrinogen control levels have been determined. The calibration curve can be examined on the screen of the analyzer in the "Calibration" menu (see the Reference Manual).

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. CALCULATIONS

The fibrinogen assay of the plasmas to be tested is automatically carried out by the analyzer as soon as the samples have been loaded. If any of the patient results falls outside the working range of the assay, the instrument automatically retests the sample in question at an appropriate dilution, provided that this option has been entered in memory in the Methodologies test setup (see the Reference Manual).

X. REPORTING RESULTS

Report results using interface/manual result entry in the LIS system.
Reference interval for UPH-Methodist for fibrinogens; 206-496 mg/dl

A. P**rocedure for Abnormal Results:**
Critical Value: <100 mg/dl
Refer to the critical values policy for how to handle critical values.

B. **Analytical Measurement Range:** 60-1800mg/dl
Results below 60 mg/dl should be turned out as <60 and those above 1800 mg/dl as >1800.

XI. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. During pregnancy there is an increase in fibrinogen level.
B. The results V>Vmax, M>Mmax, or M>MMax and V<Vmin, M<Mmin, or M<MMin are prompted on raw data (sec) selected in the Fibrinogen Methodology Setup.. If Fibrinogen is reported in concentration (mg/dL or g/L) refer to analyzer Methodology Setup and Reference Manual for result interpretation.

XII. LIMITATIONS

A. When the fibrinogen assay is to be performed on samples collected from patients receiving thrombolytic therapy, the blood samples must be collected with an anticoagulant mixture containing a plasmin inhibitor (such as aprotinin).
B. The STA® - Fibrinogen procedure is insensitive to the following substances: fibrin degradation products (up to 130 µg/ml), hirudin (up to 3 µg/ml) and heparins (UFH and LMWH) (up to 2 IU/ml).

XIII. 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

For additional information, please refer to the current manufacturer's package inserts

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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 29, 2016***

Medical Director: ***January 29, 2017***

Elizabeth A. Bauer Marsh, M.D.

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

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
0	Initial Release	Kim Paige	1/24/17
1	Changed specimen stability and made changes to the reagent Owren-Koller buffer.	Kim Paige	3/1/17

Lead	**Date**	**Coordinator**	**Date**	**Asst. Manager**	**Date**	**Medical Director**	**Date**
Kim Paige	1/17/17		1/20/17		1/17/17		1/20/17
Kim Paige	3/2/17		3/1/17				4/11/17