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

Effective: January 29, 2017
NEW

D-dimer
Sta Compact Max

I. PRINCIPLE

The test principle of this assay is based on the change in turbidity of a microparticle suspension that is measured by photometry. A suspension of latex microparticles, coated by covalent bonding with monoclonal antibodies specific for D-dimer, is mixed with the test plasma whose D-dimer level is to be assayed. An antigen-antibody reaction takes place, leading to an agglutination of the latex microparticles which induces an increase in turbidity of the reaction medium. This increase in turbidity is reflected by an increase in absorbance, the latter being measured photometrically. The increase in absorbance is a function of the D-dimer level present in the test sample.

II. CLINICAL SIGNIFICANCE

Elevated D-dimer levels are observed in all diseases and conditions with increased coagulation activation, e.g. thromboembolic disease, disseminated intravascular coagulopathy (DIC), acute aortic dissection, myocardial infarction, malignant diseases, obstetrical complications, third trimester of pregnancy, surgery or poly-trauma. The relevance of the D-Dimer assay is as an aid in the diagnosis of thromboembolic events. Elevated concentrations of D-Dimer are indicative of the presence of a clot and have been reported in deep vein thrombosis, pulmonary embolism and disseminated intravascular coagulation.

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 and 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

testing is not completed within 4 hours, the plasma must be removed, using a plastic transfer pipette. Remove the plasma to a polypropylene/plastic tube and freeze. 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 up to 4 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® - Liatest® D-Di kit

1. **Reagent 1:** Tris buffer
2. **Reagent 2:** Suspension of microlatex particles coated with two different mouse monoclonal anti-human D-dimer antibodies (8D2 and 2.1.16) then stabilized (with bovine albumin).
3. **Preparation:** Allow Reagent 1 and 2 to stand at room temperature (18-25 °C) for 15 minutes before use. Mix the reagents by gentle swirling of the vials without creating any bubbles. Then, place a new STA® - mini Reducer and the perforated cap on each vial.
4. **Storage:** The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C.
   With the STA® - mini Reducer and perforated cap in place the stability of Reagents 1 and 2 after opening and in their original vials is 15 days on ® STA Compact.

B. STA® - Liatest® Control N + P kit: provides a normal plasma and an abnormal plasma intended for the quality control of the following antigenic assays by the immuno-turbidimetric method: D-dimer assay on STA Compact® with STA® - Liatest® D-Di

1. **Reagent 1: STA® - Liatest® Control,** citrated normal human plasma, lyophilized.
2. **Reagent 2: STA® - Liatest® Control,** citrated abnormal human plasma, lyophilized.
3. **Preparation:** Reconstitute each vial of Reagent 1 or 2 with exactly 1 ml 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.
4. **Storage:** The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C, **do not freeze.**
   Once reconstituted, they remain stable for 8 hours on STA Compact®.

C. STA® - Owren-Koller 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 3 days on STA Compact®

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:
   1. **Causes severe skin burns and eye damage.**
   2. **Wear protective gloves/protective clothing/eye protection/face protection.**
   3. **IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.**
   4. **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 kits at 2-8 °C.

2. For in vitro diagnostic use only.

V. INSTRUMENTATION/EQUIPMENT

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

VI. CALIBRATION

A. Pre-calibration protocol

Kit reagents are pre-calibrated: this pre-calibration is valid for all the kits of the same lot. To enter the calibration on the analyzer, scan the barcode printed on the Assay Value insert across the barcode reader of the instrument. The calibration values for the lot of reagents being used will subsequently be validated after the two D-dimer 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

A. STA® - Liatest® Control N + P
It is necessary to run controls to ensure accuracy and reproducibility of the results. Two different levels of controls should be used. Prepare the controls and transfer to the instrument the information contained in the barcodes printed in the Assay Value insert. These controls are used undiluted.

B. If the stated control values for the lot being used cannot be reproduced, check that all the components of the test system are functioning correctly, i.e., reagents, assay conditions, etc. If necessary, repeat the tests.

VIII. PROCEDURE:

A. Patients' plasmas are tested undiluted. They are loaded in the instrument (see the Reference Manual of the analyzer model). Then select the test(s) to be performed.

B. The D-dimer assay of the plasmas to be tested is automatically carried out by the analyzer at 540 nm 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 the procedure with dilution has been chosen (see the Reference Manual).

C. Refer to START-UP 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 D-Dimer's: <0.50 ug/ml FEU's
Negative cut off for DVT and PE for D-Dimer is <0.50 ug/ml FEU's

Analytical Measurement Range: 0.27-20.0 µg/ml FEUS's

Results below 0.27 µg/ml should be turned out as <0.27 and those above 20.00 µg/ml as >20.0.
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. LIMIT OF DETECTION

The limit of detection was assessed according to CLSI guideline EP17-A (9). The limit of detection on STA Compact® is 0.27 µg/ml (FEU)

XI. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. LIMITATIONS OF THE PROCEDURE

1. Cloudy plasmas may lead to an under-estimation of the D-dimer level. (Ensure that the absorbance value at 540 nm of the plasma diluted 1:6 with STA® - Owren-Koller is < 0.35).
2. Concentrations of fibrinogen degradation products greater than 15 µg/ml may lead to an over-estimation of the D-dimer level.
3. The presence of rheumatoid factor at a level greater than 50 IU/ml may lead to an over-estimation of the D-dimer level.
4. The STA® - Liatest® D-Di is insensitive to the following substances: hemoglobin (up to 2 g/l), conjugated bilirubin (up to 290 mg/l), unconjugated bilirubin (up to 200 mg/l), unfractionated heparin (up to 2 IU/ml), and low molecular weight heparin (up to 2 anti-Xa IU/ml).
5. The presence of anti-bovine albumin and/or anti-mouse antibodies in certain subjects may lead to an over-estimation of the D-dimer level.
6. Patient with distal DVT may have a normal D-dimer level (19).
7. D-dimer assay should not be used in patients with high PTP score (19).
8. The D-dimer level increases during pregnancy and with age.

XII. 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.

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, 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 20, 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

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