HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Haematology)		
Document:	Internal Policy and Procedure		
Title:	Determination of D-Dimer by Immunoturbidimetric (Automated Method)		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-057
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-057(1)
Review Date:	February 20, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 To provide Hematology Technologists with a standard methodology for quantitative determination of cross linked fibrin degradation products (D-dimers) in human plasma

2. DEFINITONS:

N/A

3. POLICY:

3.1 D-Dimer PLUS is a latex-enhanced, immunoturbidimetric assay for the quantitative determination of cross linked fibrin degradation products (D-dimers) in human plasma.

3.2 Principle of the Method

This assay is based on the change in turbidity of a micro particle suspension that is measured by photometry. A suspension of latex micro particles, 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 micro particles 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.

4. PROCEDURE:

4.1 Specimen Collection

4.1.1 Sample collections must be in conformity with the recommendations for hemostasis tests

4.1.2 Blood (9 vol.) is collected in 0.109 M (i.e., 3.2 %) trisodium citrate anticoagulant (1 vol.) (In the USA follow CLSI guidelines H3-A5 and H21-A4).

4.1.3 Centrifugation: 15 minutes at 2000-2500 g.

4.1.4 Plasma storage: 8 hours at 20° -25 °C.
1 month at -20 °C. Frozen plasmas must be thawed directly at 37 °C for 15 minutes before testing.

4.2 Calibration

4.2.1 Kit reagent are precalibrated: this is valid for all kit of the same lot

4.2.2 To enter the calibration on the analyzer, scan the barcode printed on the assay value insert across the barcode reader of the instrument.

4.2.3 The calibration values for the lot of the reagent being used will subsequently be validated after the two ID-dimer control levels have been determinate

4.3 Patients plasmas

4.3.1 Patient's plasmas are tested undiluted. They are loaded in the instrument. Then select the test (s) to be performed.

4.4 Quality control

4.4.1 It is necessary to run controls to ensure accuracy and reproducibility of the result. Two different levels of controls should be used. Prepare the control and transfer to the instrument the information contained in barcode printed the assay value insert. These controls are used undiluted.

4.5 Assay:

4.5.1 The D-dimer assay of plasmas to be tested is automatically carried out by the analyzer at 540nm as soon as the samples have been loaded. if any of the patient results fails outside the working range of the assay .the instrument automatically retests the samples in question at an appropriate dilution provided that the procedure with dilution has been chosen

4.6 Results Interpretation

4.6.1 The relevance of the D-dimer assay is 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 coagulations. If D-dimer results are below the decision threshold, thromboembolic events can be excluded with a test specific negative predictive value (NPV).

5. MATERIALS AND EQUIPMENT:

5.1 STA® - Owren-Koller (REF 00360).

5.2 STA® - Liatest® Control +
(REF 00526): kit containing control plasmas, normal and abnormal levels.

5.3 STA® - mini Reducer (REF 00797).

5.4 Common clinical laboratory equipment and materials (centrifuge...)

5.5 Reagent 1: this buffer containing an heterophil antibody blocking agent (including rheumatoid factor

5.6 Reagent 2: suspension of microlatex particles coated with two different mouse monoclonal antihuman D-dimer antibodies then stabilized with bovine albumin)

6. RESPONSIBILITIES:

6.1 This policy applies to all Hematology technologists involved in this special Hematology test.

7. APPENDICES:

7.1 Table

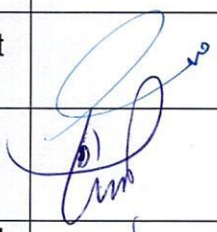
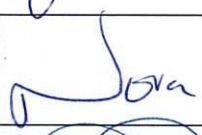
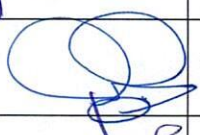
8. REFERENCES:

8.1 CRC Handbook Series in Clinical Laboratory, Science, Section 1: Hematology Volume III, 1980. CRC

8.2 Press, Inc. Boca Raton, Florida. 8.2. Budzynski AZ., Marder VJ, Parker ME, et al. Antigenic markers on fragment DD, a unique plasmic

8.3 Derivative of human crosslinked fibrin. Blood 1979; 54:794-804. 8.3. Bongard 0, Wicky J, Peter R, et al. D-Dimer plasma measurement in patients

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Fatma Hassan Ahmed	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025

Appendix 7.1

Reagents	Preparation	Stability after reconstitution/ opening on board STA Compact®	Storage position on STA Compact®
Reagent 1 (Buffer)	5-ml vial. Allow the reagent to stand at room temperature (18-25 °C) for 15 minutes. Gently homogenize without creating any bubbles. Then, place a new STA® - mini Reducer and the perforated cap.	15 days	Product drawer
Reagent 2 (Latex)	6-ml vial. Allow the reagent to stand at room temperature (18-25 °C) for 15 minutes. Gently homogenize without creating any bubbles. Then, place a new STA® - mini Reducer and the perforated cap.	15 days	Product drawer
STA® - Owren-Koller	15-ml vial. Allow the solution to stand at room temperature (18-25 °C) for 30 minutes before use.	3 days	Sample drawer
STA® - Liatest® Control N STA® - Liatest® Control P	Add exactly 1 ml of distilled water. Allow the solution to stand at room temperature (18-25 °C) for 30 minutes. Then, homogenize.	8 hours	Product drawer