HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Haematology)		
Document:	Internal Policy and Procedure		
Title:	Deficient Factors II,V,VII,X Assay		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To provide Hematology Technologists with a standard methodology for performing Determination of the activity of coagulation factor II (prothrombin), coagulation factor V, coagulation factor VII and coagulation factor X in human plasma by coagulometric methods

2. DEFINITONS:

N/A

3. POLICY:

3.1 The assay consists of the measurement of the clotting time, in the presence of the reagent, of a system in which all the factors are present, constant and in excess except factor II ,V.VII,X which is derived from the sample being tested.

4. PROCEDURE:

4.1 Specimen:

4.1.1 Collect the blood in a blue stopper vacutainer tube using a ratio of 9 parts of whole blood and 1 part of 3.2% buffered sodium citrate.

4.1.2 Centrifuge the specimen at 3500 rpm for 10 minutes.

4.1.3 Remove the platelet poor plasma and transfer to a 12 x 75 glass test tube. For the best results, test must be performed immediately.

4.1.4 Freeze the plasma at -20°C or lower until ready to test (MAX 2 weeks).

4.1.5 Frozen plasma must be thawed directly at 37°C for 15 minutes before testing

4.1.6 Specimens are stable for 4 hours at +20°C and 2 weeks at -20°C.

4.1.7 Samples that have an abnormally high hematocrit, i.e. >55%, must be re-drawn into specially modified tubes that have had the volume of anticoagulant adjusted to ensure a correct ratio of blood to anticoagulant.

4.2 Principle

4.2.1 Plasma deficient in any of the factors comprising the extrinsic pathway will result in a prolonged thromboplastin time (PT). Coagulation factor deficient plasma can be used to confirm a factor deficiency. In general, and to identify and quantify factor deficiency in patient plasma. A mixture of the respective coagulation factor deficient plasma and the patient plasma is tested in the PT assay and the result is interpreted using a reference curve obtained with dilutions of Standard Human Plasma or a normal plasma pool mixed with the deficient plasma. Patient plasma deficient in a specific factor will not be able to compensate for the absence of the factor in the corresponding coagulation factor deficient plasma and therefore result in a prolonged PT

4.3 Indication of assay: The determination of coagulation factors II.V. VII and X in plasma is indicated in the following cases:

4.3.1 Diagnosing congenital' or acquired factor deficiency states
4.3.2 Distinguishing between dysproteinemias and protein synthesis disorders (in conjunction with immunochemical methods
4.3.3 Monitoring therapy with administration of prothrombin concentrate'.
4.3.4 Detailed monitoring of therapy with oral anticoagulants
4.3.5 Testing the protein synthesis function in liver diseases

4.4 Procedural steps:
4.4.1 When the reagents are ready for use, scan the vial label bar-code across the bar-code reader.
4.4.2 Validate the reagent volume indicated by the analyzer. Then, place the vial in drawers as indicated.
4.4.3 When the beep emitted by machine this indicates to the operator that identification and position of the reagent are validated.
4.4.4 Factor II ,V,VII,V and factor X assays of the plasmas to be tested are automatically as soon as the samples have been loaded in accordance with the test definition indicated
4.4.5 If any of the patient results falls outside the working range of the assay, the machine automatically retests the sample in question at an appropriate dilution.

4.5 Results
4.5.1 The factor II .V.VII.X level (%) of the plasmas being tested is displayed in the "Test Panel/Test
4.5.2 If the control values are outside the stated ranges, check all components of the test system to ensure that all are functioning correctly, i.e., assay conditions, reagents, calibration, integrity of the plasmas being tested, etc. If necessary, repeat the assays.

5. MATERIALS AND EQUIPMENT:

5.1 Néoplastine® CI or - Néoplastine® CI Plus.
5.2 Owren-Koller.
5.3 Unicalibrator
5.4 System Control + Stirring-bar
5.5 Kit containing control plasmas, normal and abnormal levels.

6. RESPONSIBILITIES:

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

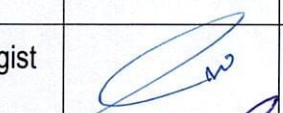
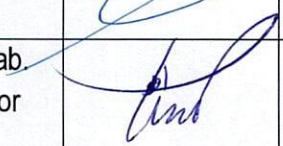
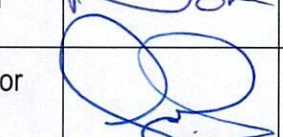
7. APPENDICES:

7.1 Reagent Preparation And Storage

8. REFERENCES:

8.1 Factor II, V, VII, and X inserts Kit

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Fatma Hassan Ahmed	Clinical Pathologist		January 07, 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 21, 2025

Appendix 7.1

REAGENT PREPARATION AND STORAGE

Reagents	Preparation	Stability after reconstitution / opening on board STA Compact®	Storage position on STA Compact®
STA® - Deficient II	Add 1 ml of distilled water. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Then, gently homogenize.	8 hours	Product drawer
STA® - Deficient V	Add 1 ml of distilled water. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Then, gently homogenize.	8 hours	Product drawer
STA® - Deficient VII	Add 1 ml of distilled water. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Then, gently homogenize.	8 hours	Product drawer
STA® - Deficient X	Add 1 ml of distilled water. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Then, gently homogenize.	8 hours	Product drawer
STA® - Néoplastine® CI or STA® - Néoplastine® CI Plus	Transfer the contents of a vial of Reagent 2 (Solvent) of the same kit. Allow the reconstituted reagent to stand at room temperature (18-25 °C) for 30 minutes. Gently homogenize. Then, place a stirring-bar, a new STA® - Reducer and the perforated cap.*	48 hours	Area with magnetic stirring-motor 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® - Unicalibrator	Add exactly 1 ml of distilled water. Allow the solution to stand at room temperature (18-25 °C) for 30 minutes. Then, homogenize.	4 hours	Product drawer
STA® - System Control N STA® - System 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