



HEALTH HOLDING

HAFAER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Haematology)		
Document:	Internal Policy and Procedure		
Title:	Clotting Assay of Protein S		
Applies To:	All Laboratory Staff		
Preparation Date:	January 07, 2025	Index No:	LB-IPP-068
Approval Date:	January 21, 2025	Version :	2
Effective Date:	February 21, 2025	Replacement No.:	LB-IPP-068 (1)
Review Date:	February 21, 2028	No. of Pages:	04

1. PURPOSE:

- 1.1 This describes the procedure for the quantitation measurement of the functional protein S level based on the principle of factor Va inhibition, in the tested plasma of the patients.

2. DEFINITONS:

- 2.1 Protein S is a vitamin –k dependent plasma protein, is the cofactor of activated protein C (protein Ca) that stimulates the proteolytic inactivation of factor Va and VIIIa by protein Ca, thereby stimulating its coagulation-inhibiting effect. Protein S occurs in plasma as free and physiologically coagulation-active protein as well as in an inactive form bound to C4b binding protein (C4bBP).

3. POLICY:

- 3.1 The principle of the assay is based upon the cofactor activity of protein S which enhances the anticoagulant action of activated protein C. This enhancement is reflected by the prolongation of the clotting time of a system enriched with factor Va, which is physiological

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 test tube labeled with patient demographic identification. 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 haematocrit, 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. For the calculation of the new volume of Na Citrate,

4.2 Procedural steps

- 4.2.1 Refer to STA Compact Operation and maintenance procedure to help you in performing the assay.

4.3 Quality Control

- 4.3.1 System Control N
- 4.3.2 System Control P.
- 4.3.3 Check values to ensure that results are within acceptable limits
- 4.3.4 Patient results cannot be released if the run is rejected based on Westguard Rules ($\pm 2SD$)
- 4.3.5 Check reagents and controls for expiration date.

- 4.4 Expected values
 - 4.4.1 55 -140 % of the normal
- 4.5 Remarks
 - 4.5.1 The test only detects the fractional activity of protein S. Reduced protein S values may be observed in deep frozen samples unless platelets and leucocytes have been carefully removed. It is best to centrifuge the samples to be frozen a second time. Presence of a factor V Leiden in the sample usually leads to reduce recovery of protein S.
- 4.6 Clinical Significance
 - 4.6.1 Screening for the risk of thrombosis
 - 4.6.2 Differential diagnosis of protein S deficiency (eg: hepatic disorders, hereditary protein S deficiency, oral anticoagulation, treatment with Lasparaginase, pregnancy, oral contraceptives, estrogen therapy and elevated plasma level as an acute-phase reaction.)

5. MATERIALS AND EQUIPMENT:

- 5.1 Reagent 1, 2 and 3.
- 5.2 STA- Owren Koller.
- 5.3 STA- CaCL₂ 0.025 M.
- 5.4 STA- Unicalibrator.
- 5.5 STA- System Control N + P.
- 5.6 Reagent Preparation:
 - 5.6.1 Reconstitute each vial of reagent 1, 2 and 3, with exactly 1 ml of distilled water. Allow the solution to stand at room temperature, (18°-25°C) for 60 minutes. Then, swirl the vial gently to obtain homogeneous solution
- 5.7 Storage:
 - 5.7.1 The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at (2°-8°C). Once reconstituted, the reagents 1, 2 and 3 remains stable for 4 hours on STA, compact, "Do not freeze".

6. RESPONSIBILITIES:

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

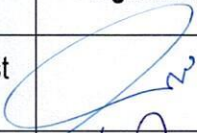
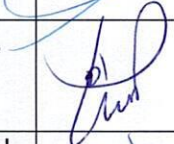




7. APPENDICES:

- 7.1 Reagent Preparation And Storage Table

8. REFERENCES:

- 8.1 STA- STAclot Protein S inserts kit.

9. APPROVALS:

	Name	Title	Signature	Date
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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®
Reagent 1 (Protein S Deficient Plasma)	Add exactly 1 ml of distilled water. Allow the solution to stand at room temperature (18-25 °C) for 60 minutes. Then, gently homogenize.	4 hours	Product drawer
Reagent 2 (PCa)	Add exactly 1 ml of distilled water. Allow the solution to stand at room temperature (18-25 °C) for 60 minutes. Then, gently homogenize.	4 hours	Product drawer
Reagent 3 (F. Va)	Add exactly 1 ml of distilled water. Allow the solution to stand at room temperature (18-25 °C) for 60 minutes. Then, gently homogenize.	4 hours	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® - CaCl₂ 0.025 M	15-ml vial. Allow the solution to stand at room temperature (18-25 °C) for 30 minutes before use.	3 days	Product 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