Current Status: *Active* **PolicyStat ID:** *9611744*

Origination: *5/13/2021*
Effective: *5/13/2021*
Last Approved: *5/13/2021*
Last Revised: *5/13/2021*
Next Review: *5/13/2023*
Document Contact: *Tamara Sabih: Medical Technologist Lead*
Area: *Laboratory-Hematology*
Key Words:
Applicability: *Royal Oak*

Qualitative Test for Fibrin Stabilizing Factor-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

Factor XIII and calcium are required for the stabilization of the fibrin polymer. In the absence of Factor XIII (Fibrin Stabilizing Factor) and calcium, the fibrin polymer is soluble in 5M urea. If plasma is clotted with calcium and the clot solubility is tested, deficiencies of Factor XIII (FSF) can be identified. This is a qualitative test and any severe Factor XIII (FSF) will be identified (<1-2%). Normal clots will survive over 24 hours.

COPY

II. SPECIMEN COLLECTION AND HANDLING:

A. Refer to the Coagulation: Specimen Collection and Handling (Non – Platelet Function Tests Only) Procedure.

III. SUPPLIES/EQUIPMENT:

A. Test tubes - 13 x 100mm, glass tubes

B. Pipettes - 1.0 mL x 0.1 and 5.0 mL x 0.1

IV. REAGENTS:

A. **Urea 5M (30%**): Add 30g Urea + 100 mL distilled water. No manufacturer's expiration date. Per known stability, frequency of use and low risk of deterioration, reagent expiration is 12 months from opening, or until expected performance is not achieved (i.e. cloudiness, color change, etc.). If performance not satisfactory, discard and make up fresh 5M urea reagent.

B. **HemosIL Calcium Chloride 0.025 (APTT-SP) reagents**: Stable until date printed on bottle. Opened reagent is stable 30 days at 2-8^{0}C in the original vial.

V. CONTROLS:

A. **Factor XIII (absent) Control Plasma:** George King FXIII deficient plasma: is citrated human plasma derived from congenital factor XIII deficient donors. When stored at -70^{0}C, it is stable for 3 years from the date of manufacture. Thaw each vial in a 37^{0}C water bath for 4 minutes. After Thawing, it is stable for 4 hours if kept at 2-8^{0}C and in the original vial, or 2 hours at room temperature.

B. **Factor XIII (present) Control Plasma:** Collected blood in 3.2% Sodium Citrate. Centrifuge (3500 RPM)

at 20-25^{o}C for 15 minutes. A patient sample may be used as a control.

VI. PROCEDURE:

A. **Preparation of Factor XIII (FXIII) deficient (absent) Control:**

1. Place 0.3 mL George King FXIII deficient plasma into 13 x 100mm glass tube.
2. Add 0.2 mL **$CaCl_2$ (0.025M) (APTT-SP)** and allow to clot at 37^{o}C for a minimum of 30 minutes.
3. Allow to clot at 37^{o}C for a minimum of 30 minutes.
4. At the end of 30 minutes, add 3.0 mL 5M urea.
5. Tap clot loose from bottom of test tube so that it floats in urea.
6. Allow tube to stand at room temperature for 24h and observe for clot lysis. Clot should dissolve within 24h.

B. **Preparation of Factor XIII (present) Control:**

1. Place 0.3 mL plasma into a 13 x 100mm glass test tube.
2. Add 0.2 mL **$CaCl_2$ (0.025M) (APTT-SP)** and allow to clot at 37^{o}C for a minimum of 30 minutes.
3. At the end of 30 minutes, add 3 mL 5M urea
4. Tap clot loose so that it floats in urea and let tube stand at room temperature for 24h.
5. At the end of 24h, observe clot.

C. **Test Procedure:**

1. Place 0.3 mL patient plasma into a 13 x 100mm glass test tube.
2. Add 0.2 mL **$CaCl_2$ (0.025M) (APTT-SP)** and allow to clot at 37^{o}C for a minimum of 30 minutes.
3. At the end of 30 minutes, add 3 mL 5M urea.
4. Tap clot loose so that it floats in urea and let tube stand at room temperature for 24h.
5. At the end of 24h, observe clot.
6. If clot is still insoluble after 24h, report as Fibrin Stabilizing Factor (Factor XIII) - present.
7. If clot has dissolved within 24h, report as Fibrin Stabilizing Factor (Factor XIII) - absent.

COPY

VII. EXPECTED VALUES:

A. **Normal Values:**

1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.

B. **Reportable Limits:**

1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.

C. **Turn Around Time:**

1. Test is performed Monday and Wednesday
2. Result available Tuesday and Thursday

VIII. REFERENCES:

A. Sirridge MS: Laboratory evaluation of hemostasis. 2nd ed, Lea and Febiger, 1974, p 150.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	5/13/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	5/13/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	5/4/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	4/19/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	4/19/2021
	Tamara Sabih: Medical Technologist Lead	4/9/2021

COPY

Applicability

Royal Oak