Beaumont Laboratory
Royal Oak

Effective Date: 10/02/2018
Supersedes: 09/09/2015
Related Documents:
RC.HM.CG.PR.001 Coagulation: Specimen Collection and Handling (Non-Platelet Function Tests Only)
RC.HM.CG.PR.002 Coagulation Tests: Reportable Limits and Normal / Therapeutic Values

QUALITATIVE TEST FOR FIBRIN STABILIZING FACTOR

RC.HM.CG.PR.031.r05

Principle

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.

Specimen Collection and Handling

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

Supplies/Equipment

Test tubes - 13 x 100mm, glass tubes
Pipettes - 1.0 mL x 0.1 and 5.0 mL x 0.1

REAGENTS:

1. **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.
2. **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.
3. **HemosIL Thrombin Time** kit consists of:
    a. **Buffer**: 1 x 9 mL vial of concentrated solution containing calcium chloride (0.5 Mol/L), buffer and preservative. Dilute the necessary quantity of concentrated Buffer 1:5 (1+4) with CLSI CLR water or equivalent[4]. Mix before use. Stability after preparation: 1 month at 15-25°C.
    b. **Bovine thrombin**: 4 x 2, 5 or 8 mL vials of lyophilized bovine thrombin (15 UNIH/vial) with bovine albumin and buffer. Dissolve the contents of each vial with 8mL of CLSI type CLR water or equivalent. Replace the stopper and swirl gently. Make sure of the completed reconstitution of the product. Keep the reagent at 15-25°C for 30 minutes and invert to mix before use. Do not shake. Stability after reconstitution: 15 days at 2-8°C

in the original vial, and 24 hours at 15°C on the ACL TOP® Family. No stirring is required.

CONTROLS:

1. Factor XIII (absent) Control Plasma: Collect blood in K_2EDTA. Centrifuge (3500 RPM) at 20-25ºC for 15 minutes. A patient sample may be used for the control.
2. Factor XIII (present) Control Plasma: Collect blood in 3.2% Sodium Citrate. Centrifuge (3500 RPM) at 20-25ºC for 15 minutes. A patient sample may be used as a control.

Run QC with each batch of patients.

Procedure

Preparation of Factor XIII deficient (absent) Control

1. Place 0.3 mL EDTA anticoagulated plasma into a 13 x 100mm glass test tube.
2. Add 0.2 mL Thrombin Time (Thrombin Time reagent from Thrombin Time procedure).
3. Allow to clot at 37ºC 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.

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) and allow to clot at 37ºC 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.

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) and allow to clot at 37ºC 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.

Expected Values

NORMAL VALUES:

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

REPORTABLE LIMITS:

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

TAT:

24 hours

References

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

Authorized Reviewers

Medical Director, Coagulation

QUALITATIVE TEST FOR FIBRIN STABILIZING FACTOR

Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Beaumont Laboratory server:
S:\HEMACOAG\Document Control\Coagulation\Procedure\Master Documents\Fibrin Stabilizing Factor
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 0
Location of circulating Controlled Copies: NA

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Sue Westley, MT(ASCP)	12/1995			
Approved by: Jacob Shanberge, MD	12/23/1995			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Jacob Shanberg, MD	12/23/1995			
Sue Westley, MT(ASCP)	01/08/1997		Reviewed.	
Joan C. Mattson, MD	01/22/1997		OK	
Joan C. Mattson, MD	12/29/1997		No change except for formatting upgrade.	
Sue Westley, MT(ASCP)	01/07/1999		Reviewed.	
Joan C. Mattson, MD	01/08/1999		No change.	
Joan C. Mattson, MD	01/24/2000		OK	
Joan C. Mattson, MD	11/28/2001		Added how to make stock urea.	
Noelle Procopio, MT(ASCP)SH	12/30/2002		Change / clarification of test tubes, pg. 1; clarification of thrombin rgt, step 2 under Procedure.	
Noelle Procopio, MT(ASCP)SH	12/29/2003		No change.	
Joan C. Mattson, MD	01/02/2004		No change.	
Noelle Procopio, MT(ASCP)SH	01/04/2005		No change.	
Joan C. Mattson, MD	05/19/2006	00	Standardized procedure format; expanded specimen collection criteria, pg. 1; changed 100x13 tubes to 13x75 mm tubes.	
Joan C. Mattson, MD	12/12/2006	01	Updated specimen handling from 4h to 2h.	
Marc Smith, MD	04/06/2007		No change.	

Marc Smith, MD	05/22/2008	02	Referred Specimen Collection and Handling. Updated equipment supplies. Added Test Thrombin reagent from Thrombin time procedure. Added Factor XIII deficient (absent) and Factor XIII (present) controls.	
Marc Smith, MD	03/12/2009		No change	
Marc Smith, MD	05/05/2010		No change	
Marc Smith, MD	06/07/2011		RC.HM added to SOP#; new format	
Marc Smith, MD	01/18/2012	03	Added 13 x 100mm glass test tube.	
Marc Smith, MD	12/22/2014		No change	OK
Marc Smith, MD	06/23/2015		No Change	OK
Marc Smith, MD	09/09/2015	04	Added urea stability.	OK
Marc Smith, MD	08/22/2017		Logo update only	OK
Elizabeth Sykes, MD	02/22/2018			
Marc Smith, MD	10/02/2018	**05**	Updated the REAGENTS: HemosIL Calcium Chloride 0.025 (APTT-SP) reagent and HemosIL Thrombin Time	OK
Peter Millward, MD	09/27/2018			