Beaumont HEALTH

Beaumont Laboratory
Royal Oak

Effective Date: 10/02/2018
Supersedes: N/A
Related Documents:
RC.HM.CG.PR.002 Coagulation Tests: Reportable Limits and Normal / Therapeutic Values
RC.HM.CG.PR.007 Coagulation Correlations
RC.HM.CG.PR.095 IL ACL TOP Operations Procedure
RC.HM.CG.PY.001 Autoverification Policy

Prothrombin Time (PT)
IL ACL-TOP

RC.HM.CG.PR.079.r00

Prothrombin Time (PT)

I. Principle

a. Prothrombin Time (PT) is the addition of tissue thromboplastin and calcium ions (PT reagent) to the patient plasma initiates the activation of the extrinsic pathway. This results in the conversion of fibrinogen to fibrin, with formation of a solid gel. The time required for clot formation is measured.
b. This product is particularly suited to the monitoring of oral anticoagulant therapy and factors of the extrinsic pathway.

II. Specimen Collection and Handling

a. Refer to Coagulation Tests: Specimen Collection and Handling (Non-Platelet Function Tests Only) procedure.

III. Supplies/Equipment

a. IL Coagulation Analyzer
b. Cuvette
c. IL Reagent racks and sample racks
d. Cleaning and Rinse solutions
e. Serological and automatic pipettes

IV. Reagents

a. Each **RecombiPlasTin 2G** kit consists of:
    i. **RecombiPlasTin 2G (RTF):** 5 x 20 mL vials of lyophilized recombinant human tissue factor, synthetic phospholipids with stabilizers, preservative and buffer. Allow each vial of reagent and diluent to equilibrate at 15-25˚C for at least 15 minutes before reconstitution. Pipette the exact

amount required 20 mL of diluent into the vial of reagent. **DO NOT POUR** the contents of the diluent vial into the vial of RecombiPlasTin 2G. Replace the stopper and swirl gently. Let sit for 15 to 20 minutes at 15-25˚C and invert to mix before use. Stability after reconstitution: 10 days at 2-8°C, 5 days at 15-25°C in the original vial or 10 days at 15°C on the ACL TOP® Family. No stir bar required.

ii. **RecombiPlasTin 2G Diluent (RTF Diluent):** 5 x 20 mL vials of an aqueous solution of calcium chloride, polybrene and a preservative.

b. **Cleaning Agent (Clean B Diluted):** Dilute Cleaning Agent 1:8 with CLSI CLRW Type (or equivalent) water (1+7).

V. Controls

a. **HemosIL Normal Control 1**: 10 x1 mL vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1mL of CLSI type CLR water or equivalent. Replace the stopper and swirl gently. Make sure of the completed reconstitution of the product. Keep the control at 15-25 C for 30 minuteds and invert to mix before use. Do not shake to avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25C^{o} onboard the ACL TOP® Family.

b. **HemosIL Abnormal Control 3**: 10 x1 mL vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1mL of CLSI type CLR water or equivalent. Replace the stopper and swirl gently. Make sure of the completed reconstitution of the product. Keep the control at 15-25 C for 30 minuteds and invert to mix before use. Do not shake to avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25C^{o} onboard the ACL TOP® Family.

VI. Quality Control

a. Quality control consists HemosIL Normal control 1 and HemosIL abnormal control 3

b. Frequency of Control Use:

i. Controls should be run at least once every 8 hours.

VII. Procedure

a. Refer to IL Coagulation operation procedure.

VIII. Expected Values

a. Any unreasonable result is to be repeated.

b. Resulting is performed in LIS.

IX. NORMAL RANGE

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

X. REPORTABLE RANGE:

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

XI. TAT

a. Routine PT orders- 90 minutes
b. STAT PT orders- 30 minutes

XII. Limitation

a. ***RecombiPlasTin 2G*** results on the ACL TOP® Family are not affected by:
   - **i.** Heparin, up to 1.0 U/Ml
   - **ii.** Hemoglobin, up to 500 mg/Dl
   - **iii.** Bilirubin, up to 30 mg/dl
   - **iv.** Triglycerides, up to 1000 mg/dl

XIII. References

a. HemosIL RecombiPlasTin 2G (PN 0020002950/0020003050) package insert
b. ACL TOP® Family On-Line Help Manual
c. Normal control 1 (PN 0020013900) package insert
d. Abnormal control 3 (PN 0020014100) package insert.

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Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Beaumont Laboratory server under S:\HEMACOAG\ Document Control\Coagulation\Procedure\Master Document\
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: Tamara Sabih, MLS(ASCP) and Rebecca Bacarella, MLS(ASCP)	09/26/2018			
Approved by: Marc Smith, MD	09/26/2018			
	Date	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Marc Smith, MD	09/26/2018	00	New Procedure for new instrumentation	
Peter Millward, MD	09/27/2018			

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