Beaumont HEALTH

Beaumont Laboratory
Royal Oak

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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

Thrombin Time (TT)
IL ACL-TOP

RC.HM.CG.PR.082.r00

Thrombin Time (TT)

I. Principle

a. This procedure provides instructions for the analysis of Thrombin Time (TT) on the ACL TOP® Family. The test is typically used for the evaluation of Disseminated Intravascular Coagulation (DIC), monitoring heparin anticoagulant and fibrinolytic therapy, detection of the presence of Fibrin/Fibrinogen Degradation Products (FDP), hereditary or acquired qualitative and quantitative fibrinogen abnormalities and increased fibrinolysis.
b. The fibrinogen in the test sample is converted to fibrin by the addition of purified bovine thrombin and the time required to form the clot is measured

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. Reagent:

a. The **HemosIL Thrombin Time** kit consists of:

i. **Buffer**: 1 x 9 mL vial of concentrated solution containing calcium chloride (0.5 Mol/L), buffer and preservative. **Dilute** the concentrated buffer 1:5 (2 mL buffer+ 8 mL DI water) with DI water or equivalent. Mix before use. Stability after preparation: 1 month at 15-25°C.

ii. **Bovine thrombin**: 4 x 2, 8 mL vials of lyophilized bovine thrombin (15 UNIH/vial) with bovine albumin and buffer. Dissolve the contents of each vial with 8mL of **diluted buffer**. 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.

V. Controls

a. **HemosIL Normal Control, ASSAYED:** 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 complete reconstitution of the product. Keep the control at 15-25C for 30 minutes and invert to mix before use. Do not shake to avoid foam formation. Reconstituted material is stable for 24 stored at 2-8 C or 15-25 C.

b. **HemosIL Low Abnormal, ASSAYED:** 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 complete reconstitution of the product. Keep the control at 15-25C for 30 minutes and invert to mix before use. Do not shake to avoid foam formation. Reconstituted material is stable for 24 stored at 2-8 C or 15-25 C.

VI. Standard

a. Calibration Plasma: 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 complete reconstitution of the product. Keep the control at 15-25C for 30 minutes and invert to mix before use. Do not shake to avoid foam formation. Reconstituted material is stable for 24 stored at 2-8 C.

VII. Quality Control

a. Quality control consists HemosIL Normal control 1 and HemosIL Low Abnormal Assayed

b. Frequency of Control Use:

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

VIII. Procedure

a. Refer to IL Coagulation operation procedure.

IX. Expected Values

a. Any unreasonable result is to be repeated.

b. Resulting is performed in LIS.

X. NORMAL RANGE

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

XI. REPORTABLE RANGE:

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

XII. TAT:

a. Routine Thrombin Time orders- 2 hours
b. STAT Thrombin Time orders- 30 minutes

XIII. Limitations

a. TT results may be affected by many commonly administered drugs. Further studies should be made to determine the source of unexpected abnormal results.
b. **The presence of hemolysis and/or lipemia is unacceptable with this assay.**
c. No interference on the ACL TOP® Family up to:
    i. Hemoglobin, up to 500 mg/dL
    ii. Bilirubin, up to 13 mg/dL

XIV. References

a. HemosIL Thrombin Time (PN 009758515) package insert
b. ACL TOP® Family On-Line Help Manual
c. Normal control 1 (PN 0020013900) package insert
d. HemosIL Low Abnormal Control ASSAYED (PN0020003210) 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)	9/2018			
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Marc Smith, MD	9/26/2018	00	New procedure for new instrumentation.	OK
Peter Millward, MD	9/27/2018			

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