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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

**Activated Partial Thromboplastin Time (aPTT)
IL ACL-TOP**

RC.HM.CG.PR.078.r00

Activated Partial Thromboplastin Time (aPTT)

I. Principle

- a. The Activated Partial Thromboplastin Time (aPTT) employs the intrinsic pathway of clotting. In the APTT test the incubation of plasma sample is incubated with an optimal quantity of phospholipids and a negatively charged contact activator and buffer initiates the activation of the intrinsic coagulation pathway. Calcium is added after incubating at 37°C for a specific period of time, and the time for clot formation is measured. The APTT included in the SynthASil kit is a liquid buffered reagent which contains synthetic phospholipid for optimal platelet –like activity and a highly defined non –setting colloidal silica for optimal activation of the contact phase of coagulation.
- b. SynthASil is sensitive to decreased concentrations of contact factors, factors in the intrinsic and common pathway, the anticoagulant effect of heparin and to the presence of inhibitors, particularly to the lupus like anticoagulant.
- c. Prolonged clotting times may be observed in the following situations: deficiency of Factor XII, XI, X, IX, VIII, V, II, or fibrinogen, liver diseases, Vitamin K deficiency, presence of heparin, lupus anticoagulant or other inhibitor.

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

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- c. IL Reagent racks and sample racks
- d. Cleaning and Rinse solutions
- e. Serological and automatic pipettes

IV. Reagents

a. HemosIL SynthASil Kit Contains:

- i. **APTT Reagent:** 5 x 10mL vials of a buffered synthetic phospholipid reagent containing a colloidal silica activator, stabilizers and a preservative. Each vial of APTT reagent must be equilibrated at 15-25°C for at least 15 minutes and mixed thoroughly before use. Opened reagents are stable 30 days at 2-8°C in the original vial and 10 days at 15°C on the ACL TOP® Family. **Do not freeze.**
- ii. **Calcium Chloride:** 5 x 10mL vials of an aqueous solution of calcium chloride (0.020 Mol/L) and a preservative. Ready for use. Opened reagent is stable 30 days at 2-30°C. 10 days at 15°C on the ACL TOP® Family. **Do not freeze.**

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 minutes and invert to mix before use. Do not shake. Avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25°C 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 minutes and invert to mix before use. Do not shake. Avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25°C 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 ACL-TOP Operation Procedure.

VIII. Expected Values

- a. Any unreasonable result is to be repeated.

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- 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 aPTT-90 minutes
- b. STAT aPTT- 30 minutes

XII. Limitation

- a. **HemosIL SynthASil** results are not affected by:
 - i. Hemoglobin up to 500 mg/Dl
 - ii. Bilirubin up to 26 mg/Dl
 - iii. Triglycerides up to 1000 mg/Dl

XIII. References

- a. HemosIL SynthASil (PN 0020006800) 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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