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

Fibrinogen Q.F.A.
IL ACL-TOP

RC.HM.CG.PR.080.r00

Fibrinogen Q.F.A.

I. Principles

a. The fibrinogen in the diluted test sample is converted to fibrin by the addition of an excess of thrombin and the resulting clotting time value is measured. The log of the clotting time value is inversely proportional to the log of the fibrinogen concentration. A fibrinogen reference curve is plotted from the clotting time results of the known referenced plasma dilutions having different fibrinogen values. The concentration of fibrinogen in patient plasma samples is determined by comparing clotting time values to the reference curve.
b. When unexplained bleeding or abnormal clotting occurs it may be of clinical importance to quantitate fibrinogen. Fibrinogen is also a useful marker in the evaluation of several disease states including Disseminated Intravascular Coagulation, liver disease and inflammatory diseases.

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 Q.F.A. Thrombin (Bovine)** kits consist of:
    i. **Q.F.A. Thrombin (Bovine)**: 10 x 2 mL (PN 0020301810) vials of lyophilized bovine thrombin (approx 100 UNIH/mL) containing buffer, an antiheparin agent and a preservative. **Allow each vial of Q.F.A. thrombin to equilibrate at 20-25 C for at least 15 minutes before reconstitution. Dissolve the contents of each vial with 2 mL with CLSI CLR water or equivalent.** Replace the stopper and swirl gently. Make sure of complete 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: 7 days at 2-8˚C or 7 days at 15°C on the ACL TOP® Family.
b. **HemosIL Factor Diluent**
c. **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 15-25Cº onboard the ACL TOP® Family.
b. **HemosIL Low Fibrinogen Control:** 10 x1 mL vials of lyophilized fresh human citrate plasma containing a reduced level of fibrinogen with buffer and stabilizer. 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 onboard the ACL TOP® Family.

VI. Quality Control

a. Quality control consists HemosIL Normal control 1 and HemosIL Low Fibrinogen control.
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. Procedure

a. Refer to IL Coagulation operation procedure.

XII. TAT

a. Routine Fibrinogen orders- 2 hours
b. STAT Fibrinogen orders- 30 minutes

XIII. Limitations

a. Fibrinogen assay results may be affected by degradation (fibrin or fibrinogen) in the plasma assayed.
b. No interference on the ACL TOP® Family up to:
    i. Hemoglobin up to 375 mg/dL
    ii. Bilirubin up to 23 mg/dL
    iii. Triglycerides up to 880 mg/dL
    iv. Heparin up to 2 U/mL

XIV. References

a. HemosIL Q.F.A. Thrombin (Bovine) (PN 0020301800) package insert
b. ACL TOP® Family On-Line Help Manual
c. Normal control 1 (PN 0020013900) package insert
d. Low Fibrinogen control (PN 0020004200) package insert.

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)	09/2018			
Approved by: Marc Smith, MD	09/26/2018			
Reviewed by: (Signature)	**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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