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

Dimer HS 500
IL ACL-TOP

RC.HM.CG.PR.081.r00

Dimer HS 500

I. Principle

a. D-Dimer is contained in the soluble derivatives formed upon plasmin degradation of Factor XIIIa cross-linked fibrin (XDP). These soluble fibrin degradation products contain a neoantigen (D-Dimer domain), which is not present on the original fibrinogen molecule, it's degradation products, or on soluble fibrin.
b. The Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with the $F(ab')_2$ fragment of a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. The use of the $F(ab')_2$ fragment allows a more specific D-Dimer detection avoiding the interference of some endogenous factors like the Rheumatoid Factor. When plasma, which contains D-Dimer, is mixed with the Latex Reagent and the Reaction Buffer included in the D-Dimer HS 500 kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

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. The **HemosIL D-Dimer HS 500** kit consists of:
   i. **Latex Reagent:** 3 x 4 mL vials of a suspension of polystyrene latex particles coated with $F(ab')_2$ fragment of a mouse antibody (MA-8D3) directed against D-Dimer. The reagent contains bovine serum albumin, buffer, stabilizers and preservative. No reconstitution necessary, gently swirl several times to mix before use. Do not shake. Avoid foam formation. Opened reagent is stable 1 month at 2-8ºC in the original vial or 7 days at 15°C on the ACL TOP® Family
   ii. **Reaction Buffer:** 3 x 6 mL vials of HEPES buffer containing bovine serum albumin, stabilizers and preservative. No reconstitution necessary, gently swirl several times to mix before use. Do not shake. Avoid foam formation. Opened reagent is stable 1 month at 2-8ºC in the original vial or 7 days at 15°C on the ACL TOP®
   iii. **NOTE:** The Latex Reagent and Reaction Buffer have the same stability claims and should be used as a pair on the instrument. If one vial is replaced the other component should also be replaced at the same time regardless of the residual content in the vial.

b. **D-Dimer Calibrator:** 2 x 1 mL vials of a lyophilized solution of D-Dimer partially purified from human fibrin digested with human plasmin. It contains bovine serum albumin, buffer, stabilizers and preservative. Dissolve the contents of each vial with 1 mL of CLSI CLR water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the reagent at 15-25ºC for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation. After reconstitution is stable for3 days at 15-25ºC, 1 month at 2-8ºC or 2 months at –20ºC in the original vial. Frozen Calibrator may be thawed at 37ºC and gently mixed before use. Do not refreeze
   i. **NOTE:** Avoid foam formation when homogenizing reconstituted calibrators or controls. Bubbles on top of the liquids may interfere with the instrument liquid sensors.

c. **HemosIL Factor Diluent:** Ready to use. Stable on instrument for 24 hours.

V. Controls:

a. The **HemosIL D-Dimer (D-D) HS 500 Controls** kit consists of:
   i. **Low D-D HS 500 Control 1:** 5 vials x 1 mL of a liquid solution of D-Dimer partially purified from human fibrin digested with human plasmin containing bovine serum albumin, buffer, stabilizers and preservatives. Controls are liquid and should be mixed by gentle inversion several times before use to assure homogeneity. Do not shake. Avoid foam formation. Bubbles on the top of the liquid may interfere with the instruments liquid sensors. Control is stable after reconstitution for 1 month at 2-8°C, 24 hours at 15-25Cº onboard the ACL TOP® Family or 3 months at –20°C in

the original vial. Frozen controls may be thawed at 37°C and gently mixed before use. Do not refreeze. **For optimal stability remove control from the system and store it at 2-8°C in the original vial.**

ii. **High D-D HS 500 Control 2:** 5 vials x 1 mL of a liquid solution of D-Dimer partially purified from human fibrin digested with human plasmin containing bovine serum albumin, buffer, stabilizers and preservatives. Controls are liquid and should be mixed by gentle inversion several times before use to assure homogeneity. Do not shake. Avoid foam formation. Bubbles on the top of the liquid may interfere with the instruments liquid sensors. Control is stable after reconstitution for 1 month at 2-8°C, 24 hours at 15-25C^{o} onboard the ACL TOP® Family or 3 months at –20°C in the original vial. Frozen controls may be thawed at 37°C and gently mixed before use. Do not refreeze. **For optimal stability remove control from the system and store it at 2-8°C in the original vial.**

VI. Standard

a. **D-Dimer Calibrator:** 2 x 1 mL vials of a lyophilized solution of D-Dimer partially purified from human fibrin digested with human plasmin. It contains bovine serum albumin, buffer, stabilizers and preservative**.** Dissolve the contents of each vial with 1 mL of CLSI CLR water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the reagent at 15-25^{o}C for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation. It is stable after reconstitution 3 days at 15-25^{o}C, 1 month at 2-8^{o}C or 2 months at –20^{o}C in the original vial. Frozen Calibrator may be thawed at 37^{o}C and gently mixed before use. Do not refreeze.

i. **NOTE:** Avoid foam formation when homogenizing reconstituted calibrators or controls. Bubbles on top of the liquids may interfere with the instrument liquid sensors.

VII. Quality Control

a. Quality control consists of Low D-Dimer HS 500, and High D-Dimer HS 500
b. Frequency of Control Use:
   i. Controls should be run at least once every 8 hours, with reagent replacement, and with a new calibration curve.

VIII. Procedure

a. Refer to IL Coagulation operation procedure.
b. Check all samples for a clot before placing on the instrument and resulting.
c. Hemolyzed, lipemic, or icteric samples must be noted with the results.

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.

XII. TAT

a. Completion of results should be available within 1hour.

XIII. Limitations

a. D-Dimer HS results are not affected by:
    i. Hemoglobin up to 500 mg/dL
    ii. Bilirubin up to 18 mg/dL
    iii. Triglycerides up to 1327 mg/dL
    iv. Rheumatoid Factor up to 1400 IU/mL

XIV. References

a. HemosIL D-Dimer HS package insert
b. HemosIL D-Dimer Controls package insert
c. ACL TOP® Family On-Line Help Manual

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			