**Dimer HS 500**

1. **Principle**
   1. 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, its degradation products, or on soluble fibrin.
   2. 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).
2. **Specimen Collection and Handling** 
   1. Refer to Coagulation Tests: Specimen Collection and Handling (Non-Platelet Function Tests Only) procedure.
3. **Supplies/Equipment** 
   1. IL Coagulation Analyzer
   2. Cuvette
   3. IL Reagent racks and sample racks
   4. Cleaning and Rinse solutions
   5. Serological and automatic pipettes
4. **Reagents**
   1. The **HemosIL D-Dimer HS 500** kit consists of:
      1. **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
      2. **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®
      3. **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.
   2. **HemosIL Factor Diluent:** Ready to use. Stable on instrument for 24 hours.
5. **Controls:**
   1. The **HemosIL D-Dimer (D-D) HS 500 Controls** kit consists of:
      1. **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 for 24 hours when placed continuously at 15-25°C onboard the ACL TOP® Family, 5 days when controls are on board for 1 hours each time, twice daily and the vials are returned well capped to 2-8°C between sessions. . 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.**
      2. **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 for 24 hours when placed continuously at 15-25°C onboard the ACL TOP® Family, 5 days when controls are on board for 1 hours each time, twice daily and the vials are returned well capped to 2-8°C between sessions. . 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.**
6. **Standard**
   1. **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 deionized (DI) water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the reagent at 15-25oC for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation. It is stable after reconstitution 3 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.
      1. **NOTE:** Avoid foam formation when homogenizing reconstituted calibrators or controls. Bubbles on top of the liquids may interfere with the instrument liquid sensors.
7. **Quality Control**
   1. Quality control consists of Low D-Dimer HS 500, and High D-Dimer HS 500
   2. Frequency of Control Use:
      1. Controls should be run at least once every 8 hours, with reagent replacement, and with a new calibration curve.
8. **Procedure**
   1. Refer to IL Coagulation Operation Procedure.
   2. Check all samples for a clot before placing on the instrument and resulting.
   3. Hemolyzed, lipemic, or icteric samples must be noted with the results.
9. **Expected Values** 
   1. Any unreasonable result is to be repeated.
   2. Resulting is performed in LIS.
10. **NORMAL RANGE**
    1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.
11. **REPORTABLE RANGE**
    1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.
12. **TAT**
    1. Completion of results should be available within 1hour.
13. **Limitations**
    1. D-Dimer HS results are not affected by:
       1. Hemoglobin up to 500 mg/dL
       2. Bilirubin up to 18 mg/dL
       3. Triglycerides up to 1327 mg/dL
       4. Rheumatoid Factor up to 1400 IU/mL
14. **References**
    1. HemosIL D-Dimer HS package insert
    2. HemosIL D-Dimer Controls package insert
    3. 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\

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**Document History**

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