Lab: D Dimer (virtual)

Skills= 7.5 Points

Objectives:

The student should be able to:

1. Observe and record a D-dimer test on two controls, one normal and one abnormal.
2. Perform a D-dimer test on one patient with 100% accuracy.
3. Properly report results with 100 % accuracy.
4. Identify the enzyme responsible for degrading fibrin.
5. List conditions with increased D-Dimers.

Materials:

1. Alere Triage Meterpro
2. Alere D-dimer test device (contains Murine monoclonal antibodies against D-dimer, Fluorescent dye, Stabilizers)
   1. Stable for up to 14 days at room temperature
2. Transfer pipet- included in the test device pouch
3. Patient sample- venous whole blood or plasma specimen using K2 EDTA
1. Gloves

Sample:

Venous whole blood or plasma specimen using K2 EDTA. If using whole blood, test patient specimen within 24 hours of sample collection. If testing cannot be completed within 24 hours, the plasma should be separated and stored at -20°C until it can be tested. Transport specimens at room temperature or chilled and avoid extreme temperatures. Avoid using severely hemolyzed specimens whenever possible.

Principle:

The Alere Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Alere Triage® Meters for the quantitative determination of cross-linked fibrin degradation products containing D-dimer.

After addition of the specimen, the whole blood cells are separated from the plasma using a filter contained in the Test Device. The specimen reacts with fluorescent antibody conjugates and flows through the Test Device by capillary action. Complexes of each fluorescent antibody conjugate are captured on a discrete zone resulting in a binding assay. The concentration of the analyte in the specimen is directly proportional to the fluorescence detected.

During the coagulation process, thrombin converts fibrinogen to soluble fibrin. Soluble fibrin spontaneously polymerizes, and the D regions are covalently cross-linked through a process that is catalyzed by factor XIIIa. Cross-linked fibrin is ultimately degraded via the fibrinolytic pathway.

Plasmin cleaves bonds in the cross-linked fibrin lattice and liberates fibrin degradation products (FDPs: X, Y, D, E)/ fibrin degradation products or fibrin split products (FSPs), including a 200 kDa cross-link of two fragment D molecules (D-dimer).

The test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism.

When a new lot of Test Devices is opened, the calibration and expiration data for that lot of Test Devices must be transferred to the Meter before patient testing. Use the Reagent CODE CHIP™ module supplied with the new lot of Test Devices to transfer the data to the Meter.

Perform one time for each new lot of Test Devices

1. From the main screen, select **Install New Code Chip**. Press **Enter**.
2. Place the Reagent CODE CHIP™ module into the lower left front corner of the Meter and follow the prompts on the screen.
3. Remove the Reagent CODE CHIP™ module from the Meter when data transfer is complete.
4. Place the Reagent CODE CHIP™ module back into its original container for storage.

Procedure:

1. Internal Control

A. Power on the Alere Triage instrument by pushing the green button.

B. From the main menu, select **RUN TEST**.

C. Select QC DEVICE.

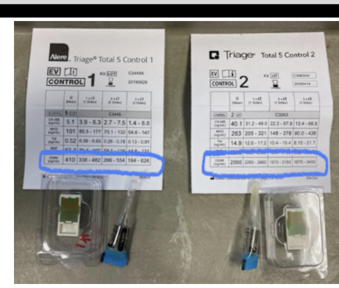
D. Slide the QC device into the instrument and press **ENTER**.
Note: the internal QC device is stored in a black housing cartridge.

E. Wait until the instrument completes testing and record results. This will take approximately 10 minutes.

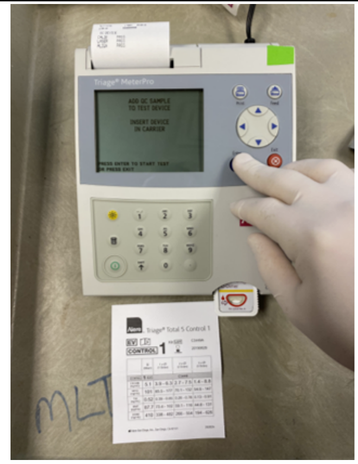
2. External Controls

A. Record the lot numbers and ranges for controls level 1 and 2
   a. Control 1: C3449A Expiration: 6/29/2019
   b. Control 2: C3563AN Expiration: 4/19/2020

   Note:
   - Align lot numbers on package insert, chip, and reagent vial to make sure the lot numbers match.
   - External controls are stored in the refrigerator and need to be thawed to room temperature before testing.



B. Open the control vial and dispense solution into sample port	
C. From the main menu, select RUN TEST then QC SAMPLE	
D. Enter control lot number into device	

E. Insert filled reagent cartridge into machine and press enter	
F. Record results for Control 1: 350 ng/mL	
G. Repeat procedure for level #2 control H. Record results for Control 2: 2580 ng/mL	

3. Patient Testing

A. Open the pouch and label the Test Device with the patient identification number.

B. Place the Test Device on a level, horizontal surface.

C. Using the transfer pipette, squeeze the larger (top) bulb completely and insert the tip into the specimen. Release the bulb slowly. The transfer pipette barrel should fill completely with some fluid flowing into the smaller (lower) bulb.

NOTE:

- *Ensure that the pipette is not under filled or over filled. An under filled pipette is one where the barrel is not filled completely with specimen and there is no specimen in the lower bulb. An over filled pipette is one where there is some specimen in the top bulb. Ideally the lower bulb should contain a small amount of specimen (less than one quarter the volume of the lower bulb).*
- Discard the transfer pipette in biohazard trash.
- Allow specimen to absorb completely before moving the Test Device. At a minimum the sample should be below the sample port opening to be considered fully absorbed.

D. From the main screen, select **Run Test** and press **Enter**.

Select **Patient Sample** and press **Enter**.

Enter the patient identification number and press **Enter**.

E. Holding the Test Device by the edges, insert the Test Device into the Meter and press **Enter**. The results will be displayed when the analysis is complete. *NOTE:* ● *The Test Device must be inserted into the Meter within 30 minutes from the time the patient specimen was added. A delay longer than 30 minutes may cause the results to be invalid and blocked out on the printout.*	
F. Record patient results of 1200 ng/mL G. Discard reagent cartridge. NOTE: ● A blocked-out result indicates the result was invalid and the test should be repeated.	

Reference Range:

The analytical reference range is 100-5,000 ng/mL. Values greater than 500 ng/mL indicate that pulmonary embolism or DVT cannot be ruled out.

Procedural Notes:

Substances such as lipids and bilirubin did not affect testing.

References:

1. McKenzie, Shirlyn B., Clinical Laboratory Hematology, pp. 785-786.
2. Powers, Lawrence W., Diagnostic Hematology, pp. 485, 490.
3. Brown, B. A., Hematology: Principles and Procedures, 5th edition, p. 219.
4. Turgeon, Mary Louise, Clinical Hematology Theory and Procedures, First edition, pp. 404-406.

    0. Alere Triage D-dimer package insert

Name______________________

Date______________________

Points =7.5

Laboratory#: D-dimer Report

**Include units on the report form.

Controls	Lot number & Expiration date	Result	Within QC Reference Range?
Control 1			
Control 2			
Patient Name	Patient ID number	Result	Within Reference Range?

Grading Rubric:
Each item is worth = 0.5 point:

- QC Lot
- QC Expiration Date
- Patient Name
- Patient identifier
- Results: Patient/QC
- Units: Patient/QC
- Addressed reference range

Name___________________

Date____________________

Points= 7

Laboratory: D-dimer

Study Questions

Directions: Using your lab, textbook, or PowerPoint material, answer the following questions.

1. What is the name of the enzyme that breaks down the fibrin clot into FDPs? (0.5pts)

0. What is the name of the inactive form of this enzyme?(0.5 pts)

0. What is another name for fibrin degradation products (FDPs)? (0.5 pts)

0. What letter designations are given to the FDPs? (2 pts)

0. What is the reference value for the "D dimer" procedure we will be performing in this lab? (1 pt)

0. State four (4) causes of an increased D-dimer? (2 pts)

0. What anticoagulant is used in the collection tube for the "D-dimer" method we will be using in this lab? (0.5 pts)