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The mLabs® D-Dimer test kit is not intended to be used as absolute evidence for PE and DVT. Obtained test results should be consulted with physician in addition with other test results.

All the provided items in the test kit are for single usage application and should be properly discarded after usage as inserted test samples may potentially be infectious.

REFERENCES

S.Z. Goldhaber. Pulmonary embolism. New England Journal of Medicine. 1998. 339: pg 93-104.

P.S. Wells, D.R. Anderson, M. Rogers et al. Evaluation of D-Dimer in the diagnosis of suspected deep-vein thrombosis. New England Journal of Medicine. 2003. 349. pgs 1227-1235.

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mLabs® D-Dimer

Rapid quantitative microfluidic assay for the detection of D-Dimer

For Health Care Professional Use Only

INTRODUCTION

When fibrin in a blood clot is broken down by enzymes in a so called fibrinolysis, a series of Fibrin Degradation Products (FDP's) are formed. One of the unique FDP's is D-Dimer, which concentration provides information helpful for diagnosing thrombosis. D-Dimer test is of significant clinical use in making diagnostic decision for patients suspected of thrombotic disorders, such as deep venous thrombosis (DVT), pulmonary embolism (PE) or disseminated intravascular coagulation (DIC).

TEST PRINCIPLE

The mLabs® D-Dimer test is based on the immunoassay technology in a microfluidic cartridge. The immunoassay technology relies on the inherent ability of an antibody to bind to the specific structure of a molecule. In the mLabs® D-Dimer microfluidic cartridge, two antibodies (reporter and capture) are carefully chosen so to have excellent specificity and

sensitivity for D-Dimer. The reporter antibody with a fluorescent dye attached is loaded in the reaction zone of the cartridge, while the capture antibody is immobilized in the detection zone. As the sample flows through, the D-Dimer in the sample first encounters and binds to the reporter antibody. As the sample continues it's marching through the detection zone, the capture antibody captures the D-Dimer reporter complex by forming a sandwich structure and remains in the detection zone, while the reporter antibody without D-Dimer is washed away. The fluorescent signal in the detection zone is proportional to the D-Dimer concentration in the sample.

MATERIALS PROVIDED

- 25 test cartridges
- 30 pipette tips
- 1 mLabs® data drive (USB-disk or SIM card)
- Instructions for use

SAMPLE COLLECTION & STORAGE

Always wear protective gloves and suitable lab coats when handling patient samples as they may potentially be infectious.

All samples should be regarded as potentially hazardous and/or contaminated.

- Collect venous samples using a 0.105M (~3.2%) Citrated Blood Collection Tube.
- Ensure that the tube is completely filled to maintain the correct anti-coagulant to blood ratio.
- Thoroughly mix the whole blood sample through gentle inversion (2-3 times) of the tube.
- Perform the whole blood test within 60 minutes of sample collection.
- Refrigerate whole blood samples if the test cannot be performed within 60 minutes after sample collection.
- Do not use syringes to collect test samples.

TEST SAMPLE STABILITY

Whole blood samples are stable at Room Temperature for a maximum of 60 minutes. Severely hemolyzed samples should be avoided.

TEST KIT STORAGE

The D-Dimer Test Kit is stable at room temperature until the listed expiration date.

The D-Dimer Test Kit should be stored at cool, dry area.

TEST PROCEDURE

1. Sample Preparation

- The mLabs® D-Dimer cartridge is only to be used together with mLabs® immunometer.
- Thoroughly mix the collected whole blood sample by gentle inverting (~2-3 times) the tube before test.

2. mLabs® ImmunoMeter Preparation

- A single mLabs® Data Drive (USB-disk or SIM card) is provided along with each kit of cartridges. Either a USB-disk (U-disk) or a SIM card can be used.
- For U-disk, please insert it into the USB port at the rear of the ImmunoMeter prior to performing test. For SIM card, please remove the SIM card from the holder and insert it into the SIM reader while the SIM reader is connected to the meter.
- From the main screen of the ImmunoMeter, as for U-disk, press "DATA DRIVES" > "UDISK"; as for SIM card, press "DATA DRIVES > "SIM".
- Once the data has been uploaded into the ImmunoMeter, the Data Drive can be removed for all subsequent related measurements.
- Store the Data Drive in a clean, dry loca-

tion for future use.

3. Sample Addition

- Remove test cartridge from pouch and label it with the patient's specifications on the front with a permanent marker.
- Using the provided test pipette, transfer 250 µL of test sample into the inlet of the test cartridge, dropwise.
- Do not place the pipette tip into the inlet during sample transfer as air bubbles may be generated. For inside mode, test the cartridge right after sample addition. For outside mode, allow at least 8 (no more than 15) minutes for the sample to interact with the reagents in the cartridge before reading.

4. Performing Test and Reading Results

- Insert the test cartridge to the cartridge holder of the mLabs® ImmunoMeter.
- Press "PATIENT TEST" from the main screen of the ImmunoMeter.
- Select the assay and sample type.
- Press "START" to start testing.
- The results will be displayed on the screen after test is complete.
- Remove and discard the used cartridge.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity
D-Dimer = 50 ng/ml

2. Measurable Range
D-Dimer = 50 to 10,000 ng/ml
3. Cut-off
D-Dimer = 500 ng/ml

Interference testing:

Hemoglobin (up to 5 mg/mL), lipids (triolein up to 30 mg/mL), bilirubin (up to 0.15 mg/mL) added to citrated-plasma containing D-Dimer did not interfere with the recovery of D-Dimer. These substances also did not generate a positive response in the absence of D-Dimer. It is noted that severely hemolyzed specimens should be avoided. Hematocrit in between 30% and 55% has no significant effect on the recovery of D-Dimer.

EXPECTED VALUES

In a study carried out using apparently healthy individuals' samples, the 95th percentile values were below 500 ng/mL. It is recommended that each laboratory should establish its own reference range.

LIMITATIONS

Carefully inspect the mLabs® D-Dimer test pouch's integrity before use. If the pouch is found to be tampered with, i.e. torn or punctured, do NOT proceed to use the test cartridge. Contact your local technical support immediately.

The mLabs® D-Dimer test kit is strictly for In Vitro Usage only. Instructions and procedures provided in this insert should be carefully