D-DIMER DEVICE

SERUM/PLASMA/WHOLE BLOOD

Intended Use:
D-Dimer Card is a rapid immunochromatography test designed for qualitative determination of D-Dimer in human whole blood, plasma and serum. This test is useful as an aid in the diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC).

Summary:
In the bloodstream, Coagulation is finalized by the formation of insoluble fibrin clot from fibrinogen.

Principle:
Fortress D-Dimer Card is immunochromatographic assay including D-Dimer specific monoclonal antibody conjugated to colloidal gold particle, second D-Dimer specific mouse monoclonal antibody, Goat anti-mouse IgG antibody conjugated to colloidal gold particle, second D-Dimer specific mouse monoclonal antibody, Goat anti-mouse IgG antibody and conjugated to colloidal gold particle. The complex migrates through a nitrocellulose membrane by capillary action and captured at test line which is second D-Dimer specific monoclonal antibody has been bound. The complex is concentrated at test line and a pink or purple line is showed if the D-Dimer concentration is higher than the clinically established cut-off. Uncaptured gold conjugate continues to flow towards control line which Goat anti-mouse IgG is bound and forms a pink or purple colour line, indicating test is working as designed and the result is valid.

Reagents:
Materials Provided:
1. Test devices
Each device is individually packaged in an aluminum pouch with desiccant.
2. Active ingredients:
D-Dimer specific mouse monoclonal antibody conjugated to colloidal gold particle, second D-Dimer specific mouse monoclonal antibody, Goat anti-mouse IgG antibody
3. Diluent: Tris-buffered saline including 0.1% sodium azide as preservative.
4. Package insert

Expected Values:
The positive results indicate the active fibrinolysis and have been shown in patients with DIC, DVT and PE. The test line is shown when D-Dimer levels are greater than 500ng/ml as measured by an Latex enhanced TIA method (D-Dimer LTIA).

Test Procedure:
1. All specimens and test devices should be at the same temperature with environment of experiments. Leave it for 15~30 minutes at room temperature before using.
2. Open the aluminum pouch and place the device on a flat horizontal surface.
3. Transfer 50uL of whole blood or 10uL of plasma, serum into the sample well. 4. Holding the bottle vertically and apply 3 drops (150uL) of Diluent to the sample well. 5. Leave the device lying flat for the incubation period and read the result at 15~20 minutes. Do not interpret test result after 20 minutes.

Specimen Collection And Preparation:
Whole blood, plasma and serum is suitable for use with D-Dimer Card. Whole blood
Sodium citrate anticoagulant is strongly recommended for use with this test. Blood samples should be stored at a refrigerator and tested within 24 hours of collection. Do not use the clotted samples for testing.

Plasma & Serum.
Fresh plasma from blood anticoagulated with sodium citrate is recommended for use with this device. After collection of blood, sample should be centrifuged and the plasma removed immediately from the blood cell interface.

Storage:
Store at 2~30°C. Do not freeze. D-Dimer card is stable until expiration dates marked on the outer packaging and pouch.

Precautions:
1. For In Vitro Diagnostic Use
2. Do not use the device past its expiration date.
3. Do not mix the components from different lot to lot.
4. Store the devices at 2~30°C. Do not freeze.
5. Before testing, leave at room temperature if you store at refrigerator.
6. Use the devices within 10 minutes after opening the aluminum pouch.
7. Do not touch the zone of membrane.
8. Diluent contains sodium azide which is react with metal ions to form highly explosive metal azides. If discarded into a sink, flush with a large quantity of water to prevent metal-azide formation.
9. All human blood products should be handled as potentially infectious materials. Wear the gloves while handling specimens.

Fistula
Plasmin
fibrin clot
Fibrinogen

D-Dimer

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Limitations Of The Procedure:
A negative result does not exclude the possibility of thrombosis. Therefore, the results obtained with D-Dimer card should be used in conjunction with clinical findings to make an accurate diagnosis.

Warning:
This device will not give correct results if the instructions for use are not strictly followed.