D-dimer Rapid Test Cassette (Whole Blood/Plasma)

**Packaging Information**
A test for the qualitative detection of D-dimer in whole blood or plasma.

**INTENDED USE**
This D-dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human D-dimer in whole blood or plasma as an aid to the diagnosis of Disseminated Intravascular Coagulation (DIC), Deep Vein Thrombosis (DVT) and pulmonary embolism (PE).

**SUMMARY**
D-dimer (or D) is a fibrin degradation product (or FDP), a small protein fragment present in the blood when a blood clot is degraded by plasmin. It is so named because it contains the cross-linked D fragments of the fibrin protein.6 D-dimer concentration may be determined by certain immunochemical methods. The use of this test in patients with suspected thrombotic disorders aids in differentiating between the patient's pretest probability and a patient with high risk for such disorders. The test result practiced rule out thrombosis, but does not rule out other potential causes. This test is intended for exudative thrombosis; where the probability is low. In addition, it is used in the diagnosis of the disseminated intravascular coagulopathy (DIC).

The D-dimer Rapid Test Cassette (Whole Blood/Plasma) is a simple test that utilizes a qualitative monoclonal antibody, encapsulated on a membrane. This test is a qualitative test for D-dimer in whole blood or plasma. The minimum detection level is 500ng/mL.

**PRINCIPLE**
The D-dimer Rapid Test Cassette (Whole Blood/Plasma) is a qualitative, membrane-based, monoclonal antibody test for the detection of D-dimer in whole blood or plasma. The membrane is pre-coated with specific antibody in the test line region of the test. During testing, the whole blood or plasma specimen reacted with specific antibodies in the test line region. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific antibody and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a positive control, a control line will always appear in the control line region indicating that proper volume of specimen has been added and membrane reaction has occurred.

**REAGENTS**
The test contains anti-D-dimer antibody conjugated gold particles and capture antibodies coated on the membrane.

**CAUTIONS**
For professional in vitro diagnostic use only. Do not use after expiration date. Do not eat, drink or smoke in the area where the specimens are handled. Do not share test if pouch is broken. Handle as specimen if they contain infectious agents. Obtain established precautions and guidelines for handling biologicals. Follow local regulations for proper disposal of reagents. Wear protective dressing, such as gloves, and eye protection when working with reagents.

**STORAGE AND STABILITY**
Store in unopened package at room temperature or refrigerated (2 to 8°C). For up to half a year, for long term storage, specimens should be kept below 20°C whole blood collected by venipuncture should not be refrigerated. For long term storage, plasma specimens may be frozen (-20°C). Whole Blood specimens should be kept below 20°C if the test is to be delayed for several days or if the sample would be too late after the occurrence of thrombosis fibrinolysis, therefore, the D-dimer concentration may decrease to below the widely accepted cutoff value. Haemolyzed specimens should not be used. For professional in vitro diagnostic use only. Do not use after expiration date.

**MATERIALS**
- **Test Cassettes**: Dropper (For whole blood and plasma)
- **Dropper**
- **Package insert**

**TEST CONDUCT**
1. **D-dimer Rapid Test Cassette (Whole Blood/Plasma)**
   - Place the cassette on a clean and level surface.
   - Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) before opening.
   - If specimens are to be shipped, they should be packed in compliance with local regulations.
   - **Negative controls** be tested as a good laboratory practice to confirm the test procedure and to compare the results of the test with a known negative specimen.
   - **Positive controls** may be run on a regular basis to ensure that the test is functioning correctly.
   - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the wrist.
   - For fingerstick:
     - Add 2 drops of whole blood to the specimen area of the test cassette.
     - Avoid air bubbles.

2. **Whole Blood specimens**
   - Add 2 drops of whole blood to the specimen area of the test cassette.
   - Start the timer and wait for 20 minutes.
   - A positive result appears when the control line (C) and test line (T) are evident.

3. **Interpretation of Results**
   - **Positive**: A colored line in the control line region (C) and the presence of one colored line in the test line region indicate a positive result. This indicates that the concentration of D-dimer is below the minimum detection level.
   - **Negative**: A white line in control line region (C) and absence of colored line in test line region (T) indicates the concentration of D-dimer is below the minimum detection level.

**LIMITATIONS**
- **D-dimer Rapid Test Cassette (Whole Blood/Plasma)** is for in vitro diagnostic use only. This test should be used for the detection of D-dimer in whole blood or plasma samples only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
- The D-dimer Rapid Test Cassette (Whole Blood/Plasma) will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulation (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

**REFERENCES**

**EXPECTED VALUES**
- **D-dimer concentration above the widely accepted cut-off value of 500ng/mL** (Fibrinogen Equivalent Unit) is a sign of an active fibrinolysis and has been verified at patients with DIC, DVT and PE, which increased concentrations are found in diseases such as inflammatory, cell lysis, liver disease, chronic infections, sepsis, infections, inflammatory, malignant disease or in older people. The concentration of D-dimer in patients with a normal pregnancy is higher than in patients with a pathological pregnancy.

**PERFORMANCE CHARACTERISTICS**
- **Sensitivity and Specificity**
  - **D-dimer Rapid Test Cassette (Whole Blood/Plasma)**
    - Results indicated relative sensitivity was 92.0%, relative specificity was 90.0%, and the overall accuracy was 90.0% compared with ITM.
    - **Clinical Study Result (In-house)**
      - **D-dimer Rapid Test Cassette (Whole Blood/Plasma)**
        - Results indicated relative sensitivity was 90.5%, relative specificity was 90.2%, and the overall accuracy was 90.0% compared with ITM.

**PHARMACOLOGY**
- **D-dimer Rapid Test Cassette (Whole Blood/Plasma)**
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  - **Clinical Study Result (In-house)**
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      - Results indicated relative sensitivity was 90.2%, relative specificity was 90.5%, and the overall accuracy was 90.0% compared with ITM.

**CONCLUSIONS**
- **D-dimer Rapid Test Cassette (Whole Blood/Plasma)**
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