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D-Dimer Test Disk

REF

Catalog No.R11-422

IVD

For In Vitro Diagnostic Use Only

For Whole Blood and Plasma

D-Dimer is a Fibrin Degradation Products (FDPs), which are formed whenever fibrin is broken down by enzymes. D-dimers are unique in that they are the breakdown products by plasmin of a fibrin mesh that has been stabilised by Factor XIII. This factor crosslinks the E-element to two D-elements. This is the final step in the generation of a thrombus. Elevated levels of D-Dimer are an indication of active fibrinolysis and have been shown in patients with disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), pulmonary emblolism.

The Rapid D-Dimer Test is a chromatographic immunoassay for the qualitative detection of D-Dimer in human whole blood and plasma. The sensitivity of the test is approximately 80ng/ml (DIMERTEST Gold EIA) or 300ng/ml (Dade Behring Stratus CS – DDMR)

Elevated concentrations of D-dimer indicated increased coagulatory and fibrinolytic activity.

MATERIALS PROVIDED

The D-Dimer test kit contains the following items to perform the assay;

1. D-Dimer test.
2. Instructions.
3. Disposable sample dropper.
4. Developing buffer.

PRECAUTIONS

The Rapid D-Dimer Test devices should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

SPECIMEN COLLECTION AND STORAGE

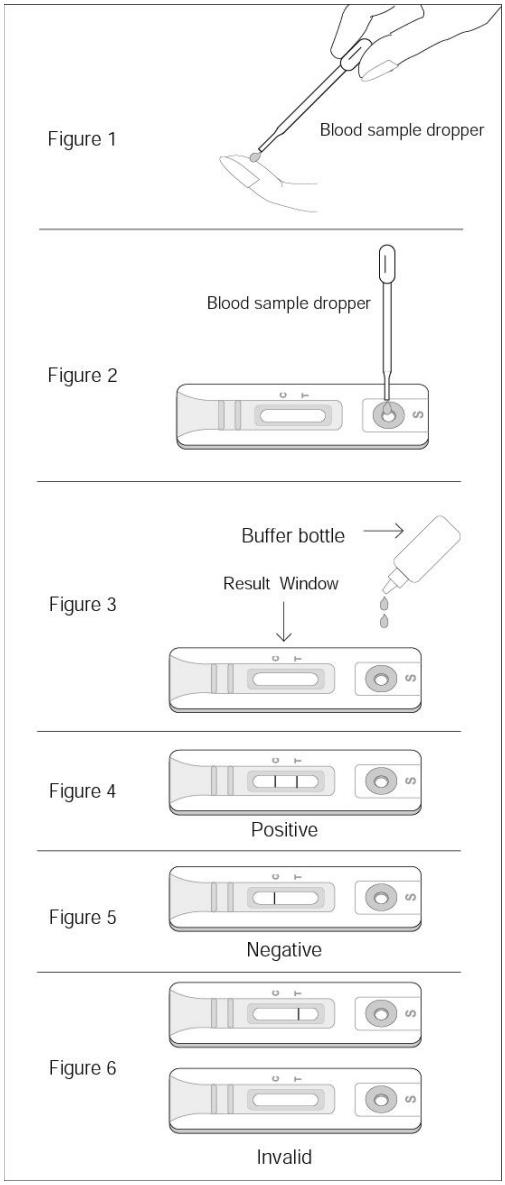
1. The test may be performed using human whole blood and plasma only.
2. Blood anticoagulated with heparin, EDTA or sodium citrate are required for whole blood collection.
3. Figure tip blood must be used immediately after collection.
4. Specimen showing evidence of clotting are not suitable for testing.
5. If specimens are not immediately tested they should be refrigerated at 2-8°C. Whole blood specimen should be tested within 24 hours, and plasma should used in 4 days. For storage periods greater up to 2 month, freezing at -2°C is recommended.
6. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Use the sample dropper to draw blood sample, fully squeeze the dropper prior drawing the sample blood (which produces a sample volume of about **20 µl of whole blood)** as shown in Figure 1, or if plasma is used, use a pipette (not provided) to draw **10µl of plasma** as sample.
3. Slowly add sample to the sample well (Figure 2).
4. Then add 2 drops of the buffer (Figure 3). As the test begins to work, you will see purple color move across the Result Window in the center of the Test Disk.
5. Interpret test results at 8 to 10 minutes. Do not interpret test result after 10 minutes.



Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 degrees C. If your

room temperature is significantly lower than 15 degrees C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

1. A color band will appear in the left section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another color band appears in the right section of the Result Window, this band is the Test Band.

POSITIVE RESULT: TWO COLOR BANDS

The presence of two bands within the Result Window, regardless of which band appears first indicates a positive result (Figure 4).

NEGATIVE RESULT: ONE COLOR BAND

The presence of only one band within the Result Window indicates a negative result (Figure 5).

INVALID RESULT:

If after performing the test no band is visible within the Result Window, the result is considered invalid (Figure 6). The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

LIMITATIONS OF THE TEST

Very high concentration of D-Dimer (greater than 60µg/ml) can lead to reduced test line intensity (prozone effect). Human anti-mouse antibodies can lead to falsely elevated results. As with all other diagnostic products, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS
COMPARISON AND SENSITIVITY STUDIES

The sensitivity of the test is approximately 80ng/ml (DIMERTEST Gold EIA) or 300ng/ml (Dade Behring Stratus CS – DDMR)

The relative sensitivity of the Immunospec D-Dimer test is 97% (174/178) and the specificity is 92% (114/122) when compared to Dade Behring Stratus CS – DDMR Immunoassay System.

SPECIFICITY AND INTERFERENCE STUDY

An in-house study is conducted on spiked plasma or whole blood Test to determine the Specificity and Interference of D-Dimer test. Compounds tested include: Plasma with triglyceride concentrations up to 500 mg/ml, Bilirubin concentrations up to 10 mg/100ml, Hemolyzed specimens with hemoglobin concentrations up to 10mg/ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

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