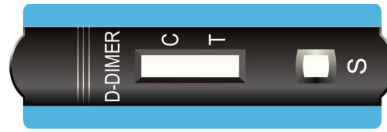


D-Dimer TEST 004A510

ulti med D-Dimer Test For Finger Stick Whole Blood and Plasma



INTRODUCTION

D-Dimer is a Fibrin Degradation Product (FDPs), which is formed when 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) and pulmonary embolism.

Elevated concentrations of D-Dimer indicate increased coagulatory and fibrinolytic activity.

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

MATERIALS PROVIDED

- D-Dimer test cassette in foil pouch (10 or 5 per kit box)
- Pipettes (10 or 5 per kit box)
- Buffer (1 per kit box)
- 1 package insert per kit box

MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch
- Alcohol pads
- Lancets

PRECAUTIONS

The ulti med D-Dimer Test devices must be stored at 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 date.

SPECIMEN COLLECTION AND STORAGE

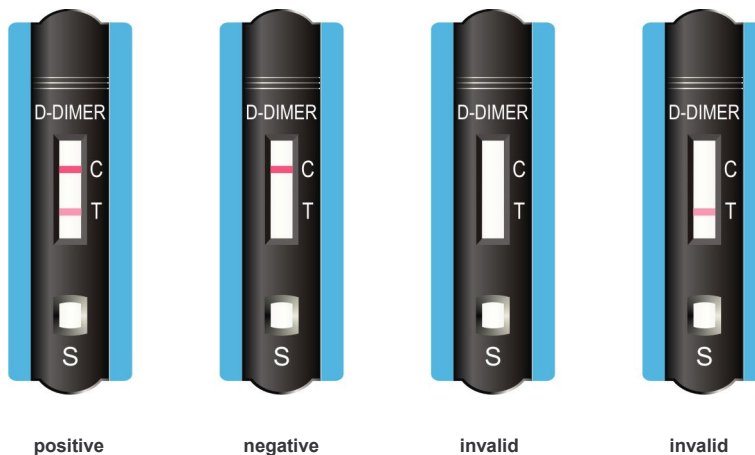
1. The test may be performed using human whole blood and plasma only.
2. Finger tip blood must be used immediately after collection.
3. Specimen showing evidence of clotting are not suitable for testing.
4. If specimens are not immediately tested they must be refrigerated at 2-8°C. Plasma should be used within 4 days. For storage periods up to 2 months, freezing at -20°C is recommended.
5. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

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

PROCEDURE

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



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Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

A coloured line will appear in the upper section of the Result Window to show that the test is working properly. This line is the Control Line (C). The lower section of the Result Window indicates the test results. If another coloured line appears in the right section of the Result Window, this line is the Test Line (T).

Positive Result: two coloured lines

The presence of two lines within the Result Window, regardless of which line appears first indicates a positive result. The Test Line intensity may vary depending on the concentration of the analyte. If the concentration is close to the cut off value, the T-line intensity may be very faint. This is nonetheless a positive result.

Negative Result: one coloured line

The presence of only one line within the Result Window indicates a negative result.

Invalid Result:

If after performing the test no Control Line (C) is visible in the Result Window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested using a new test cassette.

LIMITATIONS OF THE TEST

Very high concentration of D-Dimer (greater than 60 µg/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 must 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 80 ng/ml (DIMERTEST Gold EIA) or 300 ng/ml (Dade Behring Stratus CS – DDMR). The relative sensitivity of the 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 was conducted on spiked plasma or whole blood samples to determine the specificity and interference of D-Dimer test. Compounds tested include: Plasma with triglyceride concentrations up to 500 mg/ml, bilirubin up to 10 mg/100ml, haemolysed specimens with haemoglobin 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 analysed and did not show interference or cross reactivity with the test.

 Manufacturer	 Contents sufficient for <n> tests
 For in vitro diagnostic use only	 Lot. no.
 For single use only	 Use by
 Read instructions for use	 Store at



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