

1. INTENDED USE

The Biokits D-Dimer Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of D-dimer in human whole blood or plasma. This test is intended for professional use only.

2. INTRODUCTION

D-dimer is a specific degradation product of cross-linked fibrin formed during fibrinolysis and is an important biomarker of coagulation activation. Elevated D-dimer levels are observed in conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation (DIC), and other thrombotic disorders. Rapid detection of D-dimer aids clinicians in the early assessment and exclusion of thromboembolic events. The Biokits D-Dimer Rapid Test provides a qualitative result based on a cut-off concentration of 500 ng/mL.

3. PRINCIPLE OF THE TEST

The Biokits D-Dimer Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). D-dimer present in the sample binds to gold-conjugated anti-D-dimer antibodies and migrates along the membrane by capillary action. The D-dimer-antibody complexes are captured by immobilized anti-D-dimer antibodies at the test line region, producing a visible colored line when D-dimer concentrations are \geq 500 ng/mL. The control line is coated with polyclonal antibodies and reacts with colored microsphere control conjugate to produce a visible line independent of D-dimer concentration, confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched D-Dimer Test Devices with desiccant
2. Assay Diluent vial(s)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.

4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide an exact D-dimer concentration.
2. D-dimer levels below 500 ng/mL may not be detected.
3. Elevated D-dimer levels may be observed in non-thrombotic conditions such as infection, inflammation, pregnancy, trauma, or post-surgical states.
4. Incorrect specimen handling, insufficient sample volume, or deviation from instructions may yield invalid results.
5. Clinical decisions should not be based solely on this test; additional clinical and laboratory evaluations are required.
6. The test is validated only for human whole blood or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

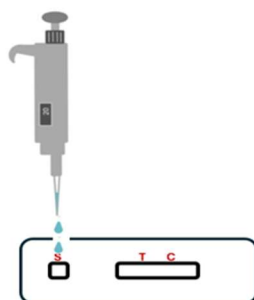
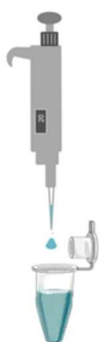
9. REFERENCES

1. Adam SS, Key NS, Greenberg CS. *D-dimer antigen: current concepts and future prospects*. Blood. 2009;113(13):2878–2887.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Whole blood (finger prick or venous) ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Finger prick or venous blood using standard procedures ✓ For plasma: centrifuge anticoagulated blood
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Add 10 ul Plasma (OR)
20 ul Whole Blood Sample
into the Dilution Buffer

Mix Well and Transfer 100 ul of
Diluted Sample into the Sample Well (S)

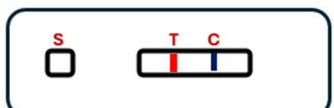
Read Results at the
end of 10 Minutes

Note: Do not read results after 10 min- it may give incorrect results !

RESULT INTERPRETATION



D-Dimer is Lesser than 500 ng/ml



D-Dimer is higher than 500 ng/ml



Invalid Test Pattern