

ACTISCREEN™ XL-FDP

Monoclonal antibody (MAb) based latex agglutination test for the qualitative and semi-quantitative measurement of cross-linked fibrin fragments (D-dimer) in human plasma. The MAb DD-3B6/22 is highly specific for D-dimer, the test is sensitive to 200 ng/mL of D-dimer.

FEATURES AND BENEFITS

- ✓ Accurate, Reliable, Low Cost
- ✓ D-dimer evaluation in three minutes
- ✓ No instrumentation required
- ✓ Perfect for emergency departments and stat situations where immediate D-dimer results are needed
- ✓ Measures only the cross linked Fibrin Degradation Products - (XL-FDP) D-dimer
- ✓ Utilizes monoclonal antibody DD3B6/22, highly specific for D-dimer^{1,2}
- ✓ No cross-reactivity with intact fibrinogen³
- ✓ Over 250 published studies referencing DD-3B6/22 make it the 'Gold Standard' MAb for *In vitro* quantitation of XL-FDP / D-dimer

ACTISCREEN™ XL-FDP

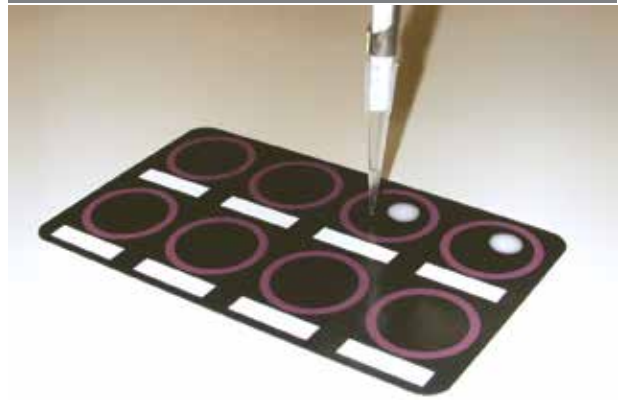
MANUAL LATEX AGGLUTINATION TEST FOR D-DIMER

IT'S AS EASY AS...

1. ADD 1 DROP OF XL_FDP LATEX



2. ADD 1 DROP OF PATIENT PLASMA



3. MIX AND INCUBATE



4. READ



The most accurate and sensitive manual XL-FDP / D-dimer test.

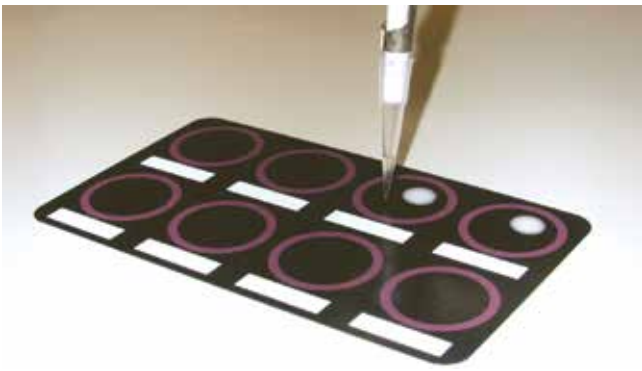
RAPID SEMI-QUANTITATIVE METHOD



1. PREPARE SERIAL DILUTIONS OF THE PATIENT PLASMA WITH BUFFER



2. PLACE ONE DROP OF LATEX REAGENT WITHIN A CIRCLE ON THE TEST CARD



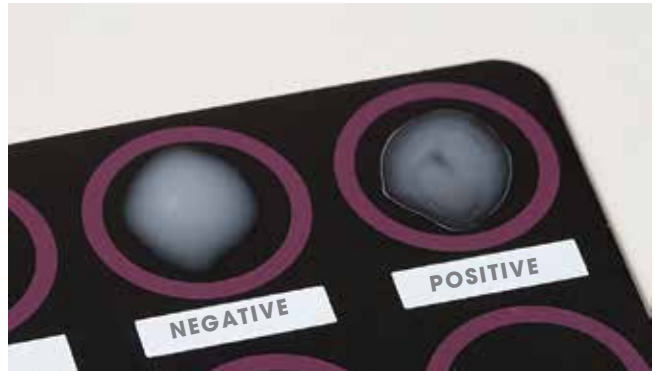
3. ADD 20 μ l OF EACH DILUTED PATIENT PLASMA OR ONE DROP OF CONTROL (NORMAL OR ABNORMAL) INSIDE THE CIRCLE, NEXT TO THE LATEX REAGENT



4. MIX THE SAMPLE (OR CONTROL) AND THE LATEX REAGENT WITH THE STIRRER PROVIDED



5. GENTLY ROCK THE TEST CARD BACK AND FORTH FOR 3 MINUTES THEN EXAMINE THE REAGENT AND SAMPLE IN THE CIRCLE



6. DETERMINE XL-FDP / D-DIMER LEVELS BASED UPON AGGLUTINATION PATTERN

MATERIALS SUPPLIED

ACTISCREEN™ XL-FDP 800DB CONTAINS:

- Latex reagent – 1 x 2,0 mL dropper bottle, white cap
- Positive control – 1 x 0,6 mL dropper bottle, yellow cap
- Negative control – 1 x 0,6 mL dropper bottle, black cap
- Buffer solution – 1 x 20 mL bottle
- Test cards – 10 each with 8 test circles
- Plastic stirrers – 60 for mixing
- Instructions for Use with qualitative and quantitative methods

ORDERING INFORMATION:

ActiScreen™ XL-FDP, **Latex kit** (60 tests) (Part No. 800DB) **IVD**

ActiScreen™ XL-FDP, **Latex vial** (60 tests) (Part No. 800DB-LX) **IVD**

MANUFACTURED IN THE USA BY:

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REFERENCES:

1. Rylatt, D.B., et al, An Immunoassay for Human D-dimer using Monoclonal Antibodies, *Thromb. Res.*, **31**(6):767-788; 1983
2. Bick, R.L., Disseminated Intravascular Coagulation: Objective Criteria for Clinical and Laboratory Diagnosis and Assessment of Therapeutic Response, *Seminars in Thrombosis & Hemostasis*, **22**(1):69-88; 1996
3. Greenberg, C.S., et al, Measurement of Plasma Fibrin D-dimer levels with the Use of a Monoclonal Antibody Coupled to Latex Beads, *Am. J. Clin. Pathol.*, **87**(1):94-100; 1987

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DIAGNOSTICS

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