ARENA BioScien

Block 5, Street 9 inside The Ismailia free zone. Ismailia- Egypt
Post Code-41511
Tel.-Fax: +202 21813500/ +202 21813600
Mob.: +2 01211550941/ +2 01119225860
E-mail: sales@arenabioscientific.com
Website: www.arenabioscien.com

FDP

Qualitative and semi-quantitative slide latex test for detecting cross-linked fibrin degradation products in human plasma

REF: BS.1/FD1.015.0015	15 tests	REF: BS.1/DIM1.020.0020	20 tests
REF: BS.1/FD1.050.0050	50 tests		

CLINICAL SIGNIFICANCE

During coagulation, a sequence of reactions occurs in the body in response to a variety of external and/or internal stimuli. The enzymatic cascade reaction terminates in the conversion of fibrinogen to fibrin by the enzyme thrombin. The fibrin gel is then converted to a stable fibrin clot by thrombin-activated Factor XIII. Finally, the fibrin network is dissolved by the enzyme plasmin to generate cross-linked fibrin degradation products ***BioScien*** FDP. D-dimer, comprising two D fragments cross-linked together, is the smallest plasmin-resistant molecular unit present within ***BioScien*** FDP.
Detection of D-dimer is invaluable as a diagnostic marker for thrombotic conditions such as DIC, DVT, and PE. D-dimer levels can also be used to monitor thrombolytic therapy with t-PA and streptokinase, thrombotic complications in pregnancy, acute myocardial infarction, sickle cell crisis, severe septic infections, liver disease, DIC from snake bites, and to monitor prognosis and response to therapy in cancer.
.

METHOD PRINCIPLE

BioScien FDP slide test for detecting cross-linked fibrin degradation products is based on agglutination. The plasma sample is mixed with the latex reagent. The sensitivity is ~200 ng/ml: below this level the result is negative, above it, positive agglutination is observed.
D-dimer, D-dimer E, and high molecular weight derivatives are recognized by the reagent. No cross-reaction was found with fibrinogen degradation products (X, Y, D, E) or fibrinogen up to 1000 mg/L.

REAGENT COMPOSITION

Reagents:	Composition
Latex Reagent	A uniform suspension of polystyrene latex particles coated with agglutinating sera for D-dimer (DD-3B6/22). Standardized to detect XL FDP >200 ng/ml.
Dilution Buffer	For performing semi-quantitative tests.
Positive Control	Reactive with the latex reagent.
Negative Control	Non-reactive with the latex reagent.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the FDP reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien FDP reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration
The ***BioScien*** FDP reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive controls.

SPECIMEN COLLECTION AND PRESERVATION

No special patient preparation needed.
Use fresh EDTA, citrate, or heparinized plasma.

Storage:
Room temp (20–25°C): up to 8 hours
Refrigerated (2–8°C): 4 days
Frozen (−20°C): 2 months

Thaw frozen samples at 37°C and centrifuge before testing.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix well before dispensing.

Qualitative procedure

1. Place one drop of plasma on the slide using the provided dropper.
2. Add one drop of latex reagent next to it.
3. Mix with a stick.
4. Rock slide and observe agglutination for 3 minutes.
5. Do not read results after 3 minutes.

Semi-quantitative method

1. Prepare serial dilutions of the test plasma with Buffer as follows:
   - 1:2 dilution: 100 µl plasma + 100 µl buffer solution
   - 1:4 dilution: 100 µl 1:2 dilution + 100 µl buffer solution
   - 1:8 dilution: 100 µl 1:4 dilution + 100 µl buffer solution
2. Add one drop of diluted plasma to each slide circle.
3. Add one drop of reagent to each.
4. Rock and observe for agglutination for 3 minutes.

READING AND INTERPRETATION

Qualitative procedure	
Positive	An agglutination of the latex particles suspension will occur within 3 minutes, indicating a (>200 ng/ml D-dimer)
Negative	No agglutination as indication for the D-Dimer level in the patient's sample is within the normal range.
Semi-Quantitative procedure	
Titer	The titer of the patient sample corresponds to the visible agglutination in the test circle with the smallest amount of sample.

Approximate Range of FDP	Sample Dilution			
	Undil.	1:2	1:4	1:8
< 0.2 (<200)	-	-	-	-
0.2 – 0.4 (200 – 400)	+	-	-	-
0.4 – 0.8 (400 – 800)	+	+	-	-
0.8 -1.6 (800 – 1600)	+	+	+	-
1.6 – 3.2* (1600 – 3200*)	+	+	+	+

"+" = agglutination, "-" = no agglutination

*Levels of XL-FDP greater than 3.20 mg/l can be estimated by further dilutions beyond 1:8

QUALITY CONTROL

The positive and negative controls have been included with the test kit to monitor the performance of the reagent. If the expected results have not been observed, the reagent should not be used. For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of FDP suspensions is 100% (+/- one double dilution).

Analytical sensitivity: Accurate titer determination of the reference material, under the described assay conditions.

Diagnostic sensitivity: 100 %.

Diagnostic specificity: 95.3 %.

LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. D-dimer half-life is ~6 hours.
4. Small clots may not raise D-dimer detectably.
5. Fibrinolysis imbalances may affect results.
6. Always correlate with clinical findings.

REFERENCES

1. Gaffney, P.J. Distinction between Fibrinogen and Fibrin Degradation Products in Plasma. Clin. Chim. Acta. 65 (1): 109-115; 1975.
2. Elms, M.J. et al. Rapid Detection of Cross-Linked Fibrin Degradation Products in Plasma using Monoclonal Antibody-Coated Latex Particles. Am. J. Clin. Pathol. 85 (3): 360-364; 1986.
3. Whitaker, A.N. et al. Measurement of Cross-Linked Fibrin Derivatives in Plasma: an Immunoassay using Monoclonal Antibodies. J. Clin. Pathol. 37 (8): 882-887; 1984.
4. Hunt, F.A. et al. Serum Crosslinked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60 (4): 715-722; 1985.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP
Medical Device Safety Service
MDSS GmbH
Schiffgr aben 41
30175 Hannover, Germany

CE