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D-DIMER

Diagnostic reagent set **(Slide latex tests)** for the in-vitro qualitative screening and semi-quantitative for the detection of circulating derivatives of cross-linked fibrin degradative products (XL-FDP) in human plasma.

REF: BS.1/DIM1.015.0015	15 tests	REF: BS.1/DIM1.025.0025	25 tests
REF: BS.1/DIM1.050.0050	50 tests	REF: BS.1/DIM1.100.0100	100 tests

CLINICAL SIGNIFICANCE

D-Dimer (DD) is the smallest fibrinolysis-specific degradation product found in the circulation. DD testing is involved in all clinical conditions in which there is hyper fibrinolysis alone or hyper fibrinolysis associated to hypercoagulation, with or without associated vascular thrombosis. For this reason, DD testing is present in several flowcharts to diagnose thrombotic disorders in particular venous thromboembolism (VTE), deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation (DIC).

METHOD PRINCIPLE

BioScien D-DIMER latex reagent is a rapid agglutination assay utilizing latex beads coupled with a highly specific D-Dimer monoclonal antibody. XL-FDP present in a plasma sample bind to the coated latex beads, which results in visible agglutination occurring when the concentration of D-Dimer is above the threshold of detection of the assay.

REAGENT COMPOSITION

Reagents:	Composition
Latex Reagent	A 0.83% suspension of latex particles coated with murine anti-D-DIMER monoclonal antibody. 10 mg/ml BSA and 0.1 % sodium azide.
Dilution Buffer	Glycine buffer, PH 7.4
Positive Control	A solution containing purified human D-DIMER fragment, 5mg/ml BSA and 0.1% sodium azide.
Negative Control	A buffer solution containing 5mg/ml BSA and 0.1% sodium azide.

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 D-DIMER reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien D-DIMER 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*** D-DIMER 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

Plasma prepared from whole blood anticoagulated with sodium citrate is recommended. The use of EDTA and heparin will result in an increased level of false positive reactions. After separation of the plasma by centrifugation (1500g for 15 minutes at 4℃ - 10°C), specimens may be tested directly for the presence of XL-FDP. Defibrination of the plasma is not recommended.
Plasma storage/stability: - 20℃: 2 weeks.
Thaw frozen specimens rapidly at 37℃ 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. Identify each reaction circle of the slide test to make one positive control, one negative control and the desired number of samples respectively.
2. Place 20 µl of the reagent within a well on a reaction slide. Avoid touching the surface of the reaction slide.
3. Place 20 µl of undiluted plasma, positive control reagents, negative control inside the same well next to the drop of latex reagent.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination macroscopically at 3 minute.

NOTE: If test reading is delayed beyond 3 minutes, the latex suspension may dry out giving a false agglutination pattern. If this is suspected, the specimen must be retested.

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.Test each dilution as described in the qualitative procedure.

READING AND INTERPRETATION

Qualitative procedure	
Positive	An agglutination of the latex particles suspension will occur within 3 minutes, indicating a D-Dimer level of more than 0.2 mg/L.
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 D-Dimer(XL-FDP) mg/l(ng/ml)	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 D-Dimer 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.

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		