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TULIP XL FDP®

A QUALITATIVE AND SEMIQUANTITATIVE LATEX SLIDE TEST
FOR DETECTING CROSS LINKED FIBRIN DEGRADATION PRODUCTS IN HUMAN PLASMA

SUMMARY

During coagulation sequence of reactions occurs in the body in response to 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 (**TULIP XL FDP®**). D dimer comprising of two D fragments cross linked together, is the smallest plasmin resistant molecular unit present within **TULIP XL 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 with streptokinase, thrombotic complications in pregnancy, acute myocardial infarction, sickle cell crisis, severe septic infections, liver disease, DIC accompanying snake bite and prognosis and response to therapy in cancer.

PRESENTATION

REF		10650015	10650060
Latex		15 Tests	60 Tests
BUF		5 ml	2 x 10 ml
Control	+	0.3 ml	0.3 ml
Control	-	0.3 ml	0.3 ml
Six circle plastic slide		1	1
Sample droppers		15	60
Mixing stick ladder		1	3
Rubber teat		1	1
Pack insert		1	1

REAGENT

1. **TULIP XL FDP® latex reagent:** A uniform suspension of polystyrene latex particles coated with Agglutinating sera for D-dimer (DD-3B6/22). The reagent is standardized to detect XL FDP ≥200 ng/ml.
2. **Positive control,** reactive with **TULIP XL FDP®** latex reagent.
3. **Negative control,** non-reactive with **TULIP XL FDP®** latex reagent.
4. **Phosphate buffer,** for performing semi quantitative test.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C.DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

PRINCIPLE

TULIP XL FDP® slide test for detection of cross-linked fibrin degradation products is based on the principle of agglutination. The test specimen (plasma) is mixed with **TULIP XL FDP®** latex reagent. The sensitivity of the reagent is ≈ 200 ng/ml, below, which samples are negative and above which samples give a positive agglutination reaction.
The cross-linked fibrin degradation products, D dimer, D dimer E, and high molecular weight derivatives are all recognized by **TULIP XL FDP®** reagent incorporating the agglutinating sera. No binding was found to the fibrinogen degradation products X, Y, D, and E to 20 mg/L or to fibrinogen upto 1000 mg/L.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagent contains 0.1% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperature conditions. It is recommended that the performance of reagent be verified with positive and negative controls supplied with the kit.

5. Shake the **TULIP XL FDP®** latex reagent vial before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection. Plasma samples are recommended for use with **TULIP XL FDP®** test. Fresh EDTA, citrate or heparinised anticoagulated plasma specimens are suitable for performing the test.

Sample storage:	20-25°C	- 8 hours
	2-8°C	- 4 days
	Frozen (-20°C)	- 2 months

Thaw frozen specimens at 37°C and centrifuge plasma before testing.

KIT COMPOSITION

1. **TULIP XL FDP®** latex reagent, positive control, negative control, PBS buffer.
2. Plastic slide with six reaction circles, disposable sample dispensing dropper, mixing sticks, rubber teat, package insert.

ADDITIONAL MATERIAL REQUIRED

Stopwatch, test tubes, high intensity direct light source.

TEST PROCEDURE

Bring all the reagents and sample to room temperature before performing the test.

QUALITATIVE METHOD

1. Pipette one drop of plasma specimen onto the plastic slide using the disposable sample dropper provided with the kit. Hold the dropper exactly in vertical position to dispense the drop accurately.
2. Add one drop of **TULIP XL FDP®** latex reagent adjacent to the drop of plasma specimen, taking care to hold the dropper in a vertical position while dispensing the drop. Do not let the dropper tip touch the plasma specimen on the slide.
3. Using a mixing stick, mix the plasma and latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch, rock the slide gently, back and forth, and observing for agglutination macroscopically at **three minutes.**
5. Do not read the test result beyond three minutes.

SEMI QUANTITATIVE METHOD

1. Using PBS buffer solution prepare serial dilutions of the plasma sample 1:2,1:4,1:8,1:16,1:32 and so on.
2. Pipette each dilutions of plasma specimen onto the separate reaction circles.
3. Add one drop of **TULIP XL FDP®** latex reagent to each drop of diluted plasma specimen onto the slide. Do not let the dropper tip touch the diluted plasma specimen on the slide.
4. Immediately start the stopwatch, Rock the slide gently, back and forth, observing for agglutination macroscopically **at three minutes.**

INTERPRETATION OF RESULTS

QUALITATIVE METHOD

Agglutination is a positive result indicating D dimer level above 200 ng/ml.

No agglutination is a negative result indicating absence of clinically significant D dimer levels in the plasma specimen.

SEMI QUANTITATIVE METHOD

Agglutination in the highest plasma dilution corresponds to the approximate amount of D dimer level in ng/ml.

To calculate D dimer level in ng/ml in the sample, use the following formula,

D dimer level (ng/ml)=200 x d

d = highest dilution of plasma showing agglutination during the semi quantitative test of the sample.

NB: Activation of the coagulation system with subsequent microvascular fibrin deposition and lysis has been reported in diverse clinical conditions such as trauma, surgery, inflammation and malignancy. Elevated levels of plasma **TULIP XL FDP®** may be expected to occur in such conditions.

REMARKS

1. D dimer half-life is approximately 6 hours in circulation of individuals with normal renal function. Patients with stabilized clots and not undergoing active fibrin deposition and plasmin activation may not give detectable D dimer elevations.
2. In PE, the larger the clot size higher the expected level of circulating D dimer. Conversely, the amount of D dimer released from very small clots may be diluted by the circulation and may not give a detectable increase.

3. Fibrinolysis is a highly regulated process and in delicate dynamic balance. In case of hereditary, acquired deficiency and dysfunction of fibrinogen, the rate of fibrinolysis will be altered thereby not giving a detectable D dimer level.
4. As with any laboratory test, detection of elevated levels of **TULIP XL FDP®** in a specimen should be correlated with clinical findings.

PERFORMANCE CHARACTERISITICS

- The performance characteristics of **TULIP XL FDP®** were evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	TULIP XL FDP®	
		+ VE	- VE
D dimer + VE samples	10	10	0
D-dimer - VE samples	65	0	65
	75	10	65

● Sensitivity: 100% ● Specificity: 100%

- Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of d-dimer negative and D-dimer positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Haemostasis and Thrombosis: Basic Principles and Clinical Practice, 3rd Edition, Edited by R.W. Colman. Jack Hirsh, Victor J. Marder, and Edwin W. Salzman. 1197-1206, J.B. Lippincott Company, 1994.
2. Mosby's Diagnostic and Laboratory Test Reference, 2nd Edition, K. D. Pagana and T.J. Pagana. Pg. 297-298. Published by Allison Miller, 1995.
3. Fibrinolysis as a feature of DIC after *Pseudonaja textilis textilis* envenomation, P.P. Masci, E.A. Rowe, A.N. Whitaker, J. de Jarsey, Thrombosis Research, Vol.59, 859-869,1990.
4. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

 Temperature limitation	 Manufacturer	 Contains sufficient for <n> tests	BUF Buffer
 Use by	 Consult Instructions for use	CONTROL + Positive control	
 Date of Manufacture	REF Catalogue Number	CONTROL - Negative control	
LOT Batch Number/ Lot Number	IVD *In vitro* Diagnostic Medical Device	REAGENT Description of reagent	
 This side up	PS Production Site	EC REP Authorised Representative in the European Community	

 **TULIP DIAGNOSTICS (P) LTD.**

PS

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