

FDP

A Qualitative And Semiquantitative Latex Slide Test For Detecting Cross Linked Fibrin Degradation Products In Human Plasma

REF. FDP-M – M02.45 (2x 0.45 ml)

SUMMARY

During coagulation sequence of reactions occur 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 (XL FDP).

D dimer comprising of two D fragments cross linked together, is the smallest plasmin resistant molecular unit present within XL FDP.

Detection of D dimer 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 tPA 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.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents contain 0.1% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal, flush with large quantities of water.
3. All the reagents 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 reagents 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 XL FDP latex reagent vial before use to disperse the latex particles uniformly and improve test readability.
6. Only clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.

KIT COMPOSITION

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

REAGENT

1. XL FDP reagent: A uniform suspension of polystyrene latex particles coated with mouse monoclonal Anti D-dimer antibody (DD-3B6/22). The reagent is standardized to detect XL FDP ≥ 200 ng/ml.
 2. Positive control, reactive with XL FDP latex reagent.
 3. Negative control, non reactive with XL FDP latex reagent.
 4. Phosphate buffer, for performing semi quantitative test.
- All the reagents contain 0.1% sodium azide as preservative. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity.

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

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 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 XL FDP reagent incorporating the monoclonal antibodies. No binding was found to the fibrinogen degradation products X, Y, D, and E to 20 mg/L or to fibrinogen up to 1000 mg/L.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection. Plasma samples are recommended for use with 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.

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 glass slide using the disposable dropper provided with the kit. Hold the dropper exactly in vertical position to dispense the drop accurately.
2. Add one drop of 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 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 positive result indicating D dimmer level above 200 ng/ml.

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

SEMI QUANTITATIVE METHOD

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

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

$$D \text{ dimmer level (ng/ml)} = 200 \times d$$

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 XL FDP may be expected to occur in such conditions.

REMARKS

1. D dimmer 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 dimmer elevations.
2. In PE, the larger the clot size, higher the expected level of circulating D dimmer. Conversely, the amount of D dimmer 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 there by not giving detectable D dimmer level.
4. As with any laboratory test, detection of elevated levels of XL FDP in a specimen should be correlated with clinical findings.

BIBLIOGRAPHY

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3. Fibrinolysis as a feature of DIC after Pseudonaja textiles textiles envenomation, P.P. Masci, E.A. Rowe, A.N. Whitaker, J.de Jarsey, Thrombosis Research, Vol.59,859-869, 1990.'

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	Caution Consult Accompanying Documents
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	Temperature Limitation
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	Batch Code
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