

## Fibrin Degradation Products In Human Plasma

**REF:**                   FDP204015   (15 test)  
                              FDP204030   (30 test)

### INTENDED FOR USE:

For the semi quantitative determination of **FDP** in plasma

### PRINCIPLE:

**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 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 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 upto 1000 mg/L.

### SPECIMEN COLLECTION:

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 (FDP).

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

### REAGENT COMPOSITIONS :

1. 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 FDP 200 ng/ml.
2. Positive control, reactive with FDP latex reagent.
3. Negative control, non reactive with 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 and performance.

### PACKAGE: Collection and storage.

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

### PRECAUTIONS & WARNING :

Avoid pipetting with mouth.

The preparation, according to current regulation, is classified as not dangerous.

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum

required for citation.

Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis.

### REAGENT PREPARATION & STABILITY :

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

### REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

### 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 20µL of FDP latex reagent adjacent to 20µL of plasma specimen
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.

### CALCULATION:

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 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 gglutination macroscopically at three minutes.

### WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

## QUALITY CONTROL:

### QUALITATIVE METHOD

Agglutination is 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 xd  
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 FDP may be expected to occur in such conditions.

## PERFORMANCE:










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 there by not giving detectable D dimer level.
4. As with any laboratory test, detection of elevated levels of FDP in a specimen should be correlated with clinical findings

## LIMITATIONS :

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 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.

## REFERENCES:

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 Diagnostics and Laboratory Test Reference, 2nd Edition, K.D. Pagana and T.J. Pagana, 297-298. Published by Allison Miller, 1995.
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.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

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