

Pacific Hemostasis® Fibrin(ogen) Degradation Products (FDP)
FDP Assay Set - FDP Control Set - FDP Latex Reagent - FDP Sample Collection Tubes
Glycine Buffered Saline

tious biological material.

I. INTENDED USE
 Pacific Hemostasis FDP Assay Set, Control Set, Latex Reagent, Glycine Buffered Saline (GBS), and Sample Collection Tubes are intended for use in the detection of Fibrinogen/Fibrin degradation products (FDP) in serum or urine.

II. SUMMARY AND PRINCIPLES

FDP are found at low levels in the sera of all healthy individuals because of normal fibrinolytic mechanisms. The mean normal level in resting adults is 4.9 ± 2.8 µg/mL.¹ Slight elevation can occur after stress, exercise, or anxiety.² Higher serum FDP levels are associated with disseminated intravascular coagulation (DIC)³, deep vein thrombosis,⁴ some pregnancy disorders^{5,6}, myocardial infarction⁷, and pulmonary embolism⁸. Urine normally contains less than 0.25 µg/mL FDP.⁹ Elevated levels can appear in renal disease such as glomerulonephritis¹⁰, and in acute graft rejection.¹¹ The Pacific Hemostasis FDP Assay Set uses direct latex agglutination to detect elevated FDP in serum or urine. Latex particles coated with anti-human fibrinogen are mixed with defibrinated serum or urine and examined for macroscopic agglutination.

III. REAGENTS

For *In Vitro* diagnostic use.
 Store all reagents at 2-8°C.

- A. **Latex Reagent:** A suspension of polystyrene latex particles sensitized with rabbit anti-human fibrinogen. Contains buffer and a preservative.
- B. **Sample Collection Tubes:** For blood or urine. Tubes contain Batroxobin, a thrombin-like enzyme that rapidly converts fibrinogen to a fibrin clot. Batroxobin is not inhibited by Anithrombin-III or heparin.^{12,13} Soybean trypsin inhibitor prevents plasmin degradation of the fibrin clot. A preservative is also added.
- C. **Glycine Buffered Saline (GBS):** Buffer with preservative.
- D. **Positive FDP Control:** >1 µg/mL human fibrinogen in glycine buffered saline with stabilizers and preservative.
- E. **Negative FDP Control:** <1 µg/mL human fibrinogen in glycine buffered saline with stabilizers and preservative.

Warning: Latex Reagent, GBS, Positive and Negative FDP Controls contain 0.1% sodium azide. Sodium azide under acid conditions yields hydrazoic acid, an extremely toxic compound. Dilute with running water before discarding, and then flush with large volumes of water. These precautions are recommended to avoid deposits in metal piping in which explosive conditions may develop.

Caution: Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found nonreactive for HBSAg and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infec-

Unexpected results or reagent color variations could indicate product deterioration. FDP Collection Tubes may fail to draw ≥ 2 mL with compatible collection systems if vacuum has been lost.

IV. SAMPLE COLLECTION

- A. **Blood:** Fill tube until the vacuum is exhausted and blood flow ceases. The exact volume of blood drawn will vary, but should be ≥ 2 mL. Alternatively, tubes can be filled by removing the stopper and adding 2-3 mL of blood. Restopper and invert gently to mix contents.
- B. Clot formation should occur soon after drawing blood. Clot retraction and serum separation can be hastened by ringing the clot or by low speed centrifugation. If sample is not centrifuged, allow it to stand at room temperature for 15-30 minutes. Heparinized blood will not cause a delay in clot retraction.
- C. Serum is best tested immediately after separation from the clot, but can be stored for up to 3 days at 2-8°C. Do not freeze.

Urine:

- A. Use only fresh, clean catch urine. The sample must not be contaminate with menstrual blood.
- B. Transfer the desired volume into the collection tube and mix by inverting.
- C. Test immediately. Do not freeze.

PROCEDURE

Materials Provided:

- Pacific Hemostasis FDP Assay Set:
- Latex Reagent: one 5 mL vial with dropper
- Positive FDP Control: one 2 mL vial with dropper
- Negative FDP Control: one 2 mL vial with dropper
- Glycine Buffered Saline: one 100 mL vial with dropper
- 30 Sample Collection Tubes, 100 mixing sticks,
- 10 Disposable test slides, 30 Plastic sampling pipets

Note: Latex Reagent (1 x 5 mL), Glycine Buffered Saline (2 x 100 mL), and FDP Sample Collection Tubes (30 or 100) can be purchased separately. Control Sets are available with 3 x 2 mL FDP Positive Control and 3 x 2 mL FDP Negative Control.

Materials Required, But Not Provided:

Glass or plastic test tubes, timer, pipets for additional dilutions, vortex.

- A. Bring all reagents and samples to room temperature.
- B. Label clean test tubes 1:10 and 1:40 for each serum sample.
- C. Urine is tested undiluted and 1:10.
- D. Using the supplied dropper, add 0.45 mL of GBS to the 1:10 tube. Add 2.0 mL to the 1:40 tube.
- E. Using a disposable Plastic Sampling Pipet, add one drop of patient sample to each tube.
- F. Rinse the disposable pipet with water and transfer one drop of the dilution(s) to separate wells on the test slide.
- G. Add one drop of Positive and Negative FDP Control to separate wells on the test slide.
- H. Vortex the capped Latex Reagent.
- I. Using the Latex Reagent dropper, add one drop to each test well.
- J. Mix with mixing sticks and spread contents to entirely fill each well.
- K. Rock the test slide gently for three minutes.
- L. Examine each well for agglutination under a direct light source. Negative wells should appear smooth. Compare all borderline wells to the Negative Control well.

VI. RESULTS

The Latex Reagent is sensitized to detect 1 µg/mL of FDP in the sample under test. Agglutination at the end of the test period indicates the presence of 1 µg/mL FDP or more in the sample under test and is reported as >1 µg/mL for undiluted urine samples, or > 10 µg/mL for 1:10 diluted serum or urine samples, or >40 for 1:40 diluted serum samples. Report results as follows:

	Urine		Serum	
	1:10	Report	1:10	Report
Undiluted				
Negative	Negative	<1 µg/mL	Negative	Negative
Positive	Positive	≥ 1 µg/mL	Positive	Negative
Positive	Positive	≥ 10 µg/mL	Positive	Positive
Positive	Positive	≥ 10 µg/mL	Positive	Positive

If a more quantitative determination is needed, continue with serial dilutions until a negative reaction is reached. FDP levels ≥ 320 µg/mL may be seen following thrombolytic therapy. At levels ≥ 400 µg/mL the 1:10 well may show negative or weak agglutination (prozone).

VII. LIMITATIONS

- A. False positive agglutination can occur in markedly lipemic or bacterially contaminated samples.
- B. The presence of rheumatoid factor (RF) can also cause false positive FDP reactions. If RF and FDP latex reagents both agglutinate, a direct interpretation of FDP levels cannot be made. Defibrinated serum samples can be reduced with dithiothreitol or 2-mercaptoethanol¹⁴ to eliminate RF.
- C. Previously frozen samples may exhibit artificially reduced FDP levels. Do not freeze.

VIII. PERFORMANCE CHARACTERISTICS

- A. Precision: Twelve serum samples over a wide range of FDP levels were tested 10 times. All samples gave identical titers on each test.
- B. Method Comparison: In correlation studies performed by independent laboratories, the Pacific Hemostasis method yielded correlation coefficients from $r = 0.84$ to 0.99 when compared to other commercial latex assays.
- C. Effect of Heparin: The Pacific Hemostasis FDP test is not affected by heparin up to 2.0 units/mL. Other tests using thrombin defibrination may detect falsely elevated FDP levels when as little as 0.1 unit/mL of heparin is present.

IX. REFERENCES

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ORDERING INFORMATION

Cat. No.	Description	Contents
100650	FDP Assay Set	30 det.
100654	FDP Sample Collection Tubes	30 tubes
101654	FDP Sample Collection Tubes	100 tubes
100651	FDP Latex Reagent	1 x 5 mL
100665	Glycine Buffered Saline	2 x 100 mL
100656	FDP Control Set	3 x 2 mL Positive 3 x 2 mL Negative

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