Bioway Chemistry Reagent Series

Fibrinogen/Fibrin Degradation Products Reagent Kit

Detection of Fibrinogen/Fibrin Degradation Products in Human Plasma on Chemistry Analyzers

Cat. No. R028K11 ***FDP Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

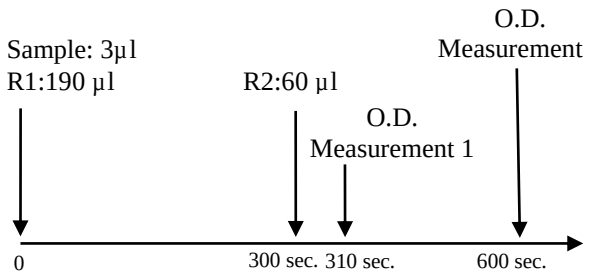

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	570 nm	Sample volume	3 µl
Test method	2 point end	R1 volume	190 µl
Reaction temperature	37℃	R2 volume	60 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Fibrinogen/Fibrin Degradation Products Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Fibrinogen/Fibrin Degradation Products in human plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Fibrinogen/Fibrin Degradation Products (FDP) are soluble protein fragments formed by clot degeneration. They are produced by the enzymatic action of plasmin on deposited fibrinogen and fibrin. Detection of FDP levels in blood is useful in diagnose of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation. Slight elevation of FDP can occur after stress, exercise and anxiety. High levels of FDP are associated with disseminated intravascular coagulation, primary fibrinolysis, pulmonary embolus, myocardial infarction, deep vein thrombosis, and some pregnancy disorders.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the FDP level in human plasma. During the test, FDP in the sample binds with the anti-FDP that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of FDP in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Buffer solution, sodium azide < 0.1%
R2	latex particles coated with anti-FDP, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. FDP calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect plasma samples.
It is recommended to perform test immediately after sample collection.
If the test cannot be done immediately, plasma sample can be stored at 2- 8° C for up to 3 days.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 3 µl of sample and 190 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Add 60 µl of R2, mix well and incubate at 37℃ for 10 seconds.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 480 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The FDP value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

0 – 10 µg/mL
It is recommended for each laboratory to establish its own expected values.

QUALITY CONTROL

Using commercially available controls with known concentration is

recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 2.5 – 80 μg/mL (R≥0.990)

Precision: Within Run: CV≤6%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Bilirubin (60 mg/dL), triglyceride (1000 mg/dL), and hemoglobin (1000 mg/dL).

Reagent Blank Absorbance: at 570 nm wavelength and 10 mm optical diameter, O.D. ≤ 1.50.

REFERENCES

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Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com