Instruction For Use

【Product Name】

FDP (eCLIA)

【Order Information】

REF NO.	Package Size
0320510201	50 T
0320510202	2×50 T
0320510203	100 T
0320510204	2×100 T

【Intended Use】

Immunoassay for the in vitro quantitative determination of fibrin/fibrinogen degradation products (FDP) in human plasma.

【Summary】

Fibrin/fibrinogen degradation products are a general term for various degradation products produced by the dissolution of fibrin/fibrinogen in the blood under the action of fibrinolytic enzymes produced during fibrinolytic hyperfunction[1]. The level of FDP can reflect the intensity of fibrinolytic activity in vivo. FDP can inhibit fibrin formation, have antithrombin effect, inhibit platelet adhesion aggregation and release[2]. Clinically, it is mainly used for the auxiliary diagnosis of primary and secondary hyperfibrinolysis related diseases, and the early diagnosis and thrombolytic therapy monitoring of deep vein thrombosis, DIC, pulmonary embolism, primary hyperfibrinolysis and other thrombotic diseases[3-5].

【Test Principle】

Sandwich principle. Total duration of assay: 9 minutes.

10 µL of sample, biotinylated monoclonal FDP antibodies, and monoclonal FDP antibodies labeled with ruthenium complex react to form a sandwich complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials (optional). Different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles, 0.45mg/mL; 0.1M PBS; ProClin300	2×1.8mL	1×1.8mL	1×3.5mL	2×3.5mL
(RB)	Biotinylated monoclonal FDP antibodies, 1.0 mg/L; PBS, ProClin300	2×3.5mL	1×3.5mL	1×7.0mL	2×7.0mL
(RA)	Monoclonal FDP antibodies labeled with ruthenium; 1.0 mg/L; PBS, ProClin300	2×3.5mL	1×3.5mL	1×7.0mL	2×7.0mL
Calibrators	FDP antigen; Freeze-dried products containing bovine serum; ProClin300	High: 1×2.0 mL Low: 1×2.0 mL			
Control Materials (Optional)	FDP antigen; Freeze-dried products containing bovine serum; ProClin300	High: 1×2.0 mL Low: 1×2.0 mL			

Traceability: This method can be traced to manufacturer's selected measurement procedures.

See the control material value sheet for the target values and ranges of control materials.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002,

【Storage and Shelf Life】

Store at 2ºC-8ºC.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened store at 2~8℃	18 months
Store at 2~8℃ after opening	8 weeks
Stored on the analyzers at 2~15℃	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and Control Materials	
Lyophilized, unopened Store at 2~8℃	18 months
Reconstituted store at 2~8℃	2 days
Reconstituted store at -15℃ or lower than -15℃	2 months (1 freeze/thaw cycles possible)

Store calibrators and control materials upright in order to prevent the calibrator from adhering to the cap of the vial.

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

It is recommended to use human plasma samples collected with sodium citrate anticoagulant blood collection tubes.

Blood samples should be collected in accordance with the standard operation of venipuncture. After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.

Samples can be stored for 8 hours at 18~28ºC, 24 hours at 2~8ºC, and 1 month at -15ºC or below. Freezing and thawing can be performed once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, one should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up FDP test according to the operational manual.

Put the FDP reagent pack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing..

Recommended ambient temperature:10~30°C; Relative humidity: ≤ 80%.

Handing of lyophilized calibrators and control materials

Carefully dissolve the contents of calibrators by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 10 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators to the additional plastic bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -15°C or lower than -15°C.

Carefully dissolve the contents of control materials by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed at room temperature for at least 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted control materials to the additional plastic bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -15°C or lower than -15°C.

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification reagent card (refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) The reagents of different lot are used.

(2) The same lot of reagents were used on the analyzer beyond 4 weeks.

(3) Quality control findings outside the defined limits.

(4) The Buffer of different lots are used.

Quality control

For quality control, use FDP Control Materials.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Please make sure that the correct values are used.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is µg/mL.

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【Biological reference interval】
By analyzing the plasma samples of healthy population, the upper limit of 95% reference interval is 5.0 μg/mL.
Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

【Interpretation of results】
When interpreting the test results, it is necessary to refer to the patient's overall clinical situation, including: symptoms, medical history as well as other corresponding data and information.

【Limitations】
The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.
The detection range of the kit is 1.0 ~ 80 μg/mL. If the FDP concentration in the sample is lower than the lower limit of detection, the result is reported as <1.0 μg/mL; if the FDP concentration in the sample is higher than the upper limit of detection, the result is reported as >80 μg/mL.
When jaundice (bilirubin) ≤ 20 mg/dL, hemolysis (hemoglobin) ≤ 500 mg/dL, lipemia (triglyceride) ≤ 2000 mg/dL, biotin ≤ 30 ng/mL, total proteins ≤ 10 g/dL, HAMA ≤ 100 ng/mL, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample ≤ 1200 IU/mL, the relative recovery of the test results is between 90% and 110%.
When the FDP concentration reaches 2000 μg/mL, there is no high-dose Hook effect.

【Analytical Performance】
Lower limit of measurement
Limit of Blank = 1.0 μg/mL.
Limit of Detection = 2.5 μg/mL.
Accuracy
The relative deviation shall not exceed ±10%.
Linearity
The correlation coefficient is not less than 0.9900 in the interval of 2.5 ~ 80 μg/mL.
Within-run precision (repeatability)
The coefficient of variation (CV) ≤8%.
Between-lot precision
The coefficient of variation (CV) ≤ 10%.
Homogeneity of calibrators and control materials
Between-bottle homogeneity: The coefficient of variation (CV) ≤ 10%.
Accuracy of calibrators
The relative deviation shall not exceed ±10%.
Measured values of control materials
The measured results of supporting assigned quality control of the kit should be within the quality control range.
Method comparison
A comparison of the Lifotronic FDP assay (y) with the commercial FDP assay method (x) using clinical samples gave the following correlations:
Number of plasma samples measured: 100
Linear regression:
y=0.9939x-0.0943
r = 0.9888
The sample concentrations were between 2.867 and 78.97 μg/mL.

【Precaution and Warning】
The kit is only used for in vitro diagnostics.
Exercise the normal precautions required for handling all laboratory reagents.
All reagents and samples including specimen, reagents, calibrators and control materials should avoid foaming before and during test.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations.
Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/ spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.

【Literature References】
1. Heene DL, Genth K. Diagnostische Bedeutung der proteolytischen Abbaupr odukte des Fibrinogens und Fibrins [Diagnostic significance of proteolytic b reakdown products of fibrinogen and fibrin]. Internist (Berl). 1984 Feb;25(2):93-101.
2. Colick JA, Fisher LM. A review of the basic mechanisms of fibrinogen to fi brin conversion and of fibrinolysis: intravascular coagulation versus primar y fibrinolysis. Va Med Mon (1918). 1970 May;97(5):310-4.
3. Isogai N, Kuroso K, Fujimaki M, Yorifuji H, Fukutake K. [Fluctuation of pl asma levels of fibrinogen degradation products, fibrin degradation products and total fibrin/fibrinogen degradation products in patients with DIC]. Rinsh o Byori. 1993 Dec;41(12):1349-52
4. Koppert PW, Kuipers W, Hoegee-de Nobel B, Brommer EJ, Koopman J, Ni euwenhuizen W. A quantitative enzyme immunoassay for primary fibrinoge
5. Takahashi H, Wada K, Takizawa S, Sakurai G, Hanano M, Niwano H, Tate waki W, Shibata A. [Evaluation of clinical usefulness of a rapid quantitative measurement of D dimer (cross-linked fibrin degradation products)]. Rinsh o Ketsueki. 1991 Dec;32(12):1533-9.

【Symbols Explanation】

Symbol	Title	Symbol	Title
	Manufacturer		Consult instructions for use
	Use-by date	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Contains sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limitation		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

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