Document ID: IFU-1758 Version: 11.0 Issue date: 2023-02-21

IVD

CE

MediRox

Instructions for Use [EN]

MRX Green FDP

REF K5016

For *In vitro* Diagnostic Use

1 Intended use

Latex immunoassay for quantitative determination of fibrin and fibrinogen degradation products (FDP) in citrated human plasma. Can be used as an aid in clinical investigations when abnormal FDP levels are suspected. Intended to be used by professional laboratory personnel using coagulation analysers with turbidimetric detection in the 500 – 700 nm wavelength range.

2 Background and principle of method

FDP is a generic name for all fragments formed during plasmin cleavage of fibrin and fibrinogen. Whereas plasmin degradation of fibrin occurs in presence of a fibrin clot, plasmin degradation of fibrinogen occurs during over-activation of the coagulation system causing systemic fibrinolysis.

During systemic fibrinolysis, seen in patients with disseminated intravascular coagulation (DIC), activated plasmin cleaves circulating fibrinogen, rendering elevated levels of fibrinogen degradation products in the blood stream.[1] FDP determination has become a common aid in the diagnosis of DIC.[2] Disorders, other than DIC, where an elevated level of FDP is seen are for example pulmonary embolism (PE), deep vein thrombosis (DVT), and acute aortic dissection (AAD).[3,4]

MRX Green FDP consists of FDP specific monoclonal antibodies coupled to sub-micron sized polystyrene particles. When the reagent is exposed to a plasma sample containing FDP, the particles will agglutinate, giving rise to increased light-scattering. When exposed to the appropriate wavelength of light, the increase in measured turbidity, or light-scattering, is proportional to the amount of FDP in the sample.

3 Components

MRX Green FDP consists of:

- Latex Reagent: 3 × 3.5 mL polystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilisers and preservatives.
- Reaction Buffer: 3 × 5 mL containing buffer and preservatives.

4 Warnings and precautions

Wear suitable clothing for protection. Avoid contact with skin and eyes. Do not empty into drains. Waste must be disposed of in accordance with local regulations.

The Latex Reagent contains Bovine Serum Albumin. The animals were approved by veterinarians by ante- and post-mortem inspections. However, as no method can offer complete assurance, this material should be handled as potentially infectious.

The Latex Reagent and Reaction Buffer contain sodium azide (less than 0.1%) and 2-methylisothiazol-3(2H)-one (less than 0.0015%) to prevent microbial growth; use proper disposal procedures.

EUH208: Contains 2-methylisothiazol-3(2H)-one. May produce an allergic reaction.

EUH210: Safety data sheet available on request.

5 Preparation

- Latex Reagent: Ready to use. As the microparticles will settle during storage, swirl the vial gently a few times every day before use to ensure a homogenous suspension. Do not shake.
- Reaction Buffer: Ready to use. Swirl the vial gently a few times before use.

Document ID: IFU-1758 Version: 11.0 Issue date: 2023-02-21

6 Storage and stability

- Latex Reagent: Store at 2 - 8 °C. Do not freeze. After opening, stable for 8 weeks at 2 - 8 °C in the closed original vial, provided no contamination occurs.
- Reaction Buffer: Store at 2 - 8 °C. Do not freeze. After opening, stable for 8 weeks at 2 - 8 °C in the closed original vial, provided no contamination occurs.

7 Specimen collection and preparation

Venous blood is collected in 3.2% sodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio). The ratio is critical. Trauma or stasis during blood sampling should be avoided. Inverse immediately after sampling. The presence of any clots in a specimen is a cause for rejection. Centrifuge to produce platelet-poor plasma and use for analysis. Refer to CLSI guideline H21-A5 for further instructions on specimen collection, handling and storage[5].

8 Procedure

For each instrument, refer to its operator's manual and to the instrument-specific application sheet.

9 Material required but not provided

Coagulation analyser capable of turbidimetric detection in the 500 - 700 nm wavelength range, pipettes and the following:

Calibrator	REF
MRX FDP Clear Calibrator Set	K5017

Control material	REF
MRX FDP Clear Low Control	K5018
MRX FDP Clear High Control	K5019

Solutions	REF
Phosphate buffered saline (PBS) for dilution, e.g. MRX PBS Diluent	K5047
Deionised water for reconstitution e.g. MRX Laboratory Water	K5036

10 Quality control

To maintain consistent assay results, it is recommended that control plasmas are assayed at regular intervals. MRX FDP Clear Controls (K5018/K5019) are recommended for MRX Green FDP. Each laboratory should establish a control range to determine the allowable variation in the day-to-day performance of the test, as well as appropriate intervals for analysing controls in accordance with good laboratory practice. Recalibration is suggested, as a minimum, whenever control plasmas are not within the acceptable range and each time a new batch of reagent is used.

11 Results

The results are reported in µg/mL FDP.

Samples that are reported above the measuring range should be manually diluted and re-analysed. No result outside the measuring range should be used in forming a diagnosis or for patient management.

12 Expected values

The normal level of FDP in the population is typically below 5 µg/mL.[6]

Results from FDP concentrations determination in plasma samples from 89 healthy blood donors using MRX Green FDP are presented below. The analysis was performed using a Sysmex CS-2100i instrument.

No of samples	Mean FDP	Mean ± 3SD
89	1.1 µg/mL	0.0 - 3.3 µg/mL FDP

As there is no internationally established standard for FDP, the concentration of FDP in any given specimen may differ when determined using FDP assays from different manufacturers. Thus, each laboratory should establish its own reference intervals or cut-off levels.

13 Limitations and interfering substances

The results should be used together with other clinical and diagnostic information in forming a diagnosis and for patient management.

Turbid or opalescent plasma may cause erratic results and should be interpreted with caution: dilute the sample and re-assay. MRX Green FDP is insensitive to the following substances on Sysmex CS-instrument series:

IVD CE

Interfering substance	Tolerance
Bilirubin	Up to 40 mg/dL
Haemoglobin	Up to 1000 mg/dL
Triglycerides	Up to 1500 mg/dL
Unfractionated heparin	Up to 330 U/dL
Low molecular weight heparin	Up to 330 U/dL

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA), which may cause over-estimation of FDP values. The presence of rheumatoid factor may also result in falsely elevated FDP values.

The monoclonal antibody in MRX Green FDP has been screened for its specificity. MRX Green FDP has a high specificity for fibrin- and fibrinogen degradation products. MRX Green FDP does not bind to pure fibrin fragment E, nor fibrinogen fragment D or E.

14 Analytical performance characteristics

The following performance data was obtained with a Sysmex CS-2100i instrument. Performance will depend on the instrument used.

MRX Green FDP has a measuring range of 3.0 - 135 µg/mL FDP. There is no prozone effect below 500 µg/mL FDP. When compared to another microparticle enhanced immunoassay, MRX Green FDP correlates as follows:

y (Stago Liatest FDP on Sysmex CS-2100i) = 1.001 x (MRX Green FDP on Sysmex CS-2100i) - 1.004; r^2 = 0.953.

Precision:

Sample	Mean FDP	Repeatability CV
Level 1	13.2 µg/mL	3.8%
Level 2	34.3 µg/mL	2.1%

15 Reporting of incidents

Any serious incidents that occur in relation to this device shall be reported to Nordic Biomarker as well as the national competent authority in which the user is established.

16 Additional information

A paper copy of these Instructions for Use is available on request. Contact your local distributor.
The instrument-specific application sheet is available from your local distributor.

17 References

1. GANDO, Satoshi; LEVI, Marcel; TOH, Cheng-Hock. Disseminated intravascular coagulation. *Nature Reviews Disease Primers*, 2016, 2.1: 1-16.
2. TOH, C. H.; HOOTS, W. K.; SSC ON DISSEMINATED INTRAVASCULAR COAGULATION OF THE ISTH. The scoring system of the Scientific and Standardisation Committee on Disseminated Intravascular Coagulation of the International Society on Thrombosis and Haemostasis: a 5-year overview 1. *Journal of Thrombosis and Haemostasis*, 2007, 5.3: 604-606.
3. MORESCO, Rafael Noal, et al. D-dimer and its relationship to fibrinogen/fibrin degradation products (FDPs) in disorders associated with activation of coagulation or fibrinolytic systems. *Journal of clinical laboratory analysis*, 2003, 17.3: 77-79.
4. NAGAOKA, Kazuhiro, et al. Fibrinogen/fibrin degradation products in acute aortic dissection. *Internal Medicine*, 2010, 49.18: 1943-1947.
5. CLSI. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline – Fifth Edition. CLSI document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
6. MIRSHAHI, Massoud, et al. A latex immunoassay of fibrin/fibrinogen degradation products in plasma using a monoclonal antibody. *Thrombosis research*, 1986, 44.6: 715-728.

18 Definition of symbols

	Manufacturer	 nordicbiomarker.com/IFU	Consult electronic instructions for use
	CE mark		Use-by date
	In vitro diagnostic medical device		Temperature limit
	Catalogue number		Biological risks
	Batch code		Contains biological material of animal origin

19 Revision history

Version	Changes to previous version
11.0	Section 14: Editorial update of measuring range and correlation equation.