

MRX FDP 550 nm Art. No: MRX132

INTENDED USE

MRX FDP 550 nm is a latex immunoassay (LIA) for the quantitative determination of fibrin and fibrinogen degradation products (FDP) in human plasma. MRX FDP 550 nm is suitable for automatic coagulation and clinical-laboratory instruments using turbidimetric detection in the 500 - 650 nm wavelength range. **FOR IN VITRO DIAGNOSTIC USE ONLY.**

BACKGROUND AND PRINCIPLE OF METHOD

The product is used for quantitative determination of FDP in human plasma. 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 stream¹.

The determination of FDP has become a prevalent aid in the diagnosis of DIC². Disorders where an elevated level of FDP is seen are, besides DIC, for example pulmonary embolism (PE), deep vein thrombosis (DVT), and acute aortic dissection (AAD)^{3,4}.

The MRX FDP 550 nm reagent consists of sub-micron sized polystyrene particles coupled to monoclonal antibodies specific for FDP. When the reagent is exposed to an FDP containing plasma sample, 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.

PRODUCT DESCRIPTION

MRX FDP 550 nm Latex Reagent: 5 x 5 mL polystyrene particles, coated with monoclonal antibodies, suspended in a buffer with preservatives and stabilizers.

MRX FDP 550 nm Reaction Buffer: 5 x 9 mL containing buffer, preservatives and stabilizers.

PRECAUTIONS

Only for *in vitro* diagnostic use. The reagent contains bovine serum albumin, derived from animals free from infectious and contagious diseases and inspected ante- and post mortem by a veterinarian. As precaution, the material should, however, be treated as potentially infectious. MRX132 should be handled by trained laboratory personnel only. Wear suitable clothing for protection. Avoid contact with skin and eyes. Waste is disposed of according to local regulations. Do not empty into drains. Detailed information can be found in the Material Safety Data Sheet.

PREPARATION

MRX FDP 550 nm Latex Reagent: Ready to use. Swirl the vial gently before use to ensure homogenous suspension as the micro-particles will settle during storage.

MRX FDP 550 nm Reaction Buffer: Ready to use.

STORAGE CONDITIONS AND STABILITY

MRX FDP 550 nm Latex Reagent: Unopened reagent stored at 2 – 8 °C is stable until the expiration date shown on the vial. Opened reagent stored at 2 – 8 °C is stable for 4 weeks, in the closed original vial, provided no contamination occurs.

MRX FDP 550 nm Reaction Buffer: Unopened reaction buffer stored at 2 – 8 °C is stable until the expiration date shown on the vial. Opened reaction buffer stored at 2 – 8 °C is stable for 4 weeks, in the closed original vial, provided no contamination occurs.

PROCEDURE

For each instrument, refer to its operator's manual and to the instrument-specific MRX FDP 550 nm application sheet. FDP Clear Calibrator (MRX1207) should be used for calibration of reagent. The user must complete a reference curve for each new lot of reagents and/or if control plasma falls outside the assigned limits.

SPECIMEN COLLECTION AND STORAGE

Citrated plasma is used for testing. It is recommended that specimen collection, handling and storage is carried out in accordance with CLSI guideline H21-A5 Vol. 28 No.5⁵. Venous blood is collected in 3.2 % sodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio).

MATERIAL REQUIRED BUT NOT PROVIDED

MRX1207: FDP Clear Calibrator level 1 to 5
 MRX191: FDP Clear Low Control
 MRX192: FDP Clear High Control
 MRX184: Sample Diluent

QUALITY CONTROL

Medirox recommends the use of FDP Clear Low Control (MRX191) and FDP Clear High Control (MRX192) for reliable quality control of the assay performance and at a frequency in accordance with good laboratory practise. Each laboratory should establish its own quality control program to evaluate its measurement methods including the current reagent.

RESULTS

The results are reported in µg/mL FDP.

LIMITATIONS AND INTERFERENCES

MRX FDP 550 nm reagent is insensitive to the following substances: hemoglobin up to 2000 mg/dL, bilirubin up to 50 mg/dL, triglycerides up to 2190 mg/dL, unfractionated heparin 110 U/mL and low molecular weight heparin up to 1100 U/mL. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA). Such antibodies may cause an over-estimation of FDP values. The presence of rheumatoid factor may result in false positive results. Turbid or opalescent plasma may cause erratic results and should be interpreted with caution; dilute the sample and re-assay.

EXPECTED VALUES

The normal level of FDP in the population is typically below 5 µg/mL⁶. However, as there is no internationally established standard for FDP, the concentration of FDP in any given specimen may differ if using FDP assays from other manufacturers. Each laboratory should establish its own reference intervals or cut-off levels.

PERFORMANCE CHARACTERISTICS

The performance will depend on the instrument used. Refer to the instrument-specific MRX FDP 550 nm application sheet for details. The performance data below was obtained using a Sysmex CS2100i instrument.

Precision

The precision of MRX FDP 550 nm reagent was determined for one lot of reagent and evaluated according to CLSI guideline EP05-A3⁷ using low and high FDP plasma samples, containing different levels of FDP.

MRX132	Mean (µg/ml FDP)	Repeatability (CV %)	Intra-device (CV %)
Low FDP sample	13.2	3.8	4.2
High FDP sample	34.3	2.1	2.6

Limit of quantification (LoQ) and linearity

The LoQ and linearity for MRX FDP 550 nm were determined for one lot of reagent and evaluated according to the guidelines in CLSI EP17-A2⁸ and CLSI EP06-A⁹, respectively.

MRX132	FDP (µg/ml)
LoQ	3.0
Linearity	0.9 – 113

REFERENCES

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