

MRX Free Protein S Art. No: MRX153

INTENDED USE

MRX Free Protein S (MRX FPS) is a latex immunoassay (LIA) for the quantitative determination of free protein S (FPS) in human plasma. MRX FPS is suitable for automatic coagulation and clinical-laboratory instruments using turbidimetric detection in the 600 - 800 nm wavelength range. **FOR IN VITRO DIAGNOSTIC USE ONLY.**

BACKGROUND AND PRINCIPLE OF METHOD

The product is used for quantitative determination of FPS in human plasma. Quantitative determination of FPS in human plasma is used in clinical investigations of different diseases, e.g. acquired protein S deficiency which can be caused by several disorders and treatments^{1,2,3}. Protein S is a vitamin K dependent glycoprotein with anticoagulant properties^{4,5,6} and in the presence of calcium, protein S acts as a cofactor to, and forms a complex with activated protein C (APC). The complex adheres to negatively charged phospholipid membranes which increases the anticoagulant activity of APC^{6,7}.

The normal total concentration of protein S in human plasma is in the range 20 – 25 mg/L; approximately two thirds of this is bound to C4b-binding protein (C4BP), whereas the remaining non-bound fraction is FPS².

MRX FPS consists of sub-micron sized polystyrene particles coupled to two different monoclonal antibodies specific for Protein S. This system is not sensitive to protein S bound to C4BP, and only reacts with FPS. When the reagent in MRX FPS is exposed to a plasma sample containing FPS, 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 FPS in the sample.

PRODUCT DESCRIPTION

MRX FPS Latex Reagent: 3 x 2.5 mL polystyrene particles, coated with monoclonal antibodies, suspended in a buffer with preservatives and stabilizers.

MRX FPS Buffer: 3 x 4 mL containing buffer, preservatives and stabilizers.

PRECAUTIONS

Only for *in vitro* diagnostic use. MRX153 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 FPS Latex Reagent: Ready to use. Swirl the vial gently before use (to ensure homogenous suspension as the micro-particles will settle during storage).
MRX FPS Reaction Buffer: Ready to use.

STORAGE CONDITIONS AND STABILITY

MRX FPS 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 FPS 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 FPS application sheet.

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.5⁸. 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

MRX1206: FPS Calibrator

MRX184: Sample Diluent

Normal and abnormal control plasmas, see quality control.

QUALITY CONTROL

MediRox recommends the use of normal control plasma (GHI164 or MRX181) and abnormal control plasma (GHI170, MRX182 and MRX183) for reliable quality control of the assay performance and at a frequency in accordance with good laboratory practice. Each laboratory should establish its own quality control program to evaluate its measurement methods including the current reagent.

RESULTS

The results are reported in % FPS, where 100 % corresponds to 1 IU/mL FPS of the 2nd WHO International Standard (NIBSC code 03/228).

LIMITATIONS AND INTERFERENCES

MRX FPS reagent is insensitive to the following substances: hemoglobin up to 10 g/L, bilirubin up to 0.8 g/L, triglycerides up to 30 g/L, unfractionated and low molecular weight heparin up to 100 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 the results. 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. The monoclonal antibodies in MRX FPS have been screened for their specificity for FPS. When purified C4BP is added to normal plasma samples, in amounts stoichiometrically equivalent to the normal FPS plasma concentration, the signal reported by MRX FPS is fully quenched.

EXPECTED VALUES

Expected values were determined by quantification of the FPS concentration in plasma samples from 122 healthy female blood donors and 138 healthy male blood donors. Analysis were performed using a Sysmex CS2100i. This is only to be seen as a guideline, each laboratory should establish its own local reference range for FPS measurements.

MRX153	Females	Males
Number of samples	122	138
Mean (%)	81.5	93.6
Lower limit of expected value (%)	34.8	55.8
Upper limit of expected value (%)	128.1	131.3

PERFORMANCE CHARACTERISTICS

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

Precision

The precision of MRX FPS reagent was determined according to CLSI guideline EP05-A3⁹ using three different pools of plasma containing different levels of FPS.

MRX153	Mean (% FPS)	Repeatability (CV %)	Intra-device (CV %)
Plasma pool level 1	95.0	2.69	4.01
Plasma pool level 2	44.8	1.30	2.83
Plasma pool level 3	25.1	1.62	3.01

Limit of quantification (LoQ) and linearity

The LoQ and linearity for MRX FPS were determined for one lot of reagent and evaluated according to the guidelines in CLSI EP17-A2¹⁰ and CLSI EP06-A1¹¹, respectively.

MRX153	FPS (%)
LoQ	4.2
Linearity	20 – 150

REFERENCES

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