

## Free Protein S Calibrator Art.No: MRX1206, MRX1206-10

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### INTENDED USE

Free Protein S Calibrator, MRX1206 is intended for calibration of Free Protein S reagent, MRX153.

**FOR IN VITRO DIAGNOSTIC USE ONLY.**

### BACKGROUND AND PRINCIPLE OF METHOD

The calibrator plasma is used to generate a calibration curve for quantitative determination of free protein S (FPS) in human citrated plasma. FPS results are reported in % FPS, where 100 % corresponds to 1 IU/mL FPS of the 2<sup>nd</sup> WHO International Standard for protein S (NIBSC 03/228).

### PRODUCT DESCRIPTION

FPS Calibrator consists of 1 mL lyophilized human plasma with a specified level of FPS. Each lot of calibrator is assayed and assigned against an in-house master, traceable to 2<sup>nd</sup> WHO International Standard for protein S (NIBSC 03/228). Refer to the vial label and product certificate for lot-specific FPS level.

MRX1206	1*1 mL
MRX1206-10	10*1 mL

### PRECAUTIONS

Only for *in vitro* diagnostic use. MRX1206 should be handled by trained laboratory personnel only. Wear suitable clothing for protection. Avoid contact with skin and eyes. The calibrator contains material of human origin. Each donor has been tested by approved methods and found negative for the presence of HBsAg and anti-HIV I & II and anti-HCV. However, as no method can offer complete assurance that infectious agents are absent, this material should be handled as any potentially infectious material.

### PREPARATION

Reconstitute the content of each vial with 1 mL of CLSI CLRW type water or equivalent<sup>1</sup>. Keep the calibrator at 15-25 °C for 30 minutes. Replace the stopper and mix gently by swirling or inverting several times until the content is completely reconstituted.

### STORAGE CONDITIONS AND STABILITY

Unopened calibrator stored at 2 – 8 °C is stable until expiration date shown on the vial. Reconstituted calibrator is stable for 24 hours at 20 – 25 °C, in closed original vial, provided no contamination occurs.

### PROCEDURE

For each instrument, refer to its operator's manual and to the instrument-specific application sheet on how to use FPS Calibrator. The user must complete a reference curve for each new lot of reagents and/or if control plasma falls outside the assigned limits.

### MATERIAL REQUIRED BUT NOT PROVIDED

MRX153: MRX FPS Reagent  
 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 practise. Each laboratory should establish its own quality control program to evaluate its measurement methods.

### LIMITATIONS

This product is designed for calibration of MRX FPS reagent. The calibration plasma is subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

### TRACEABILITY OF CALIBRATOR REFERENCE VALUES

The specified FPS level for the FPS calibrator is assayed and assigned against an in-house master, traceable to 2<sup>nd</sup> WHO International Standard for protein S (NIBSC 03/228).

### REFERENCES

1. Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical Laboratory, Fourth Edition, CLSI Document C3-A4; Vol. 26 No. 22, 2012