

FDP Clear Calibrator Art.No: MRX1207

INTENDED USE

FDP Clear Calibrator, MRX1207 is intended for calibration of MRX FDP 550 nm reagent, MRX132.

FOR IN VITRO DIAGNOSTIC USE ONLY.

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.

PRODUCT DESCRIPTION

FDP Clear Calibration Kit consists of five vials with different levels of human-derived fibrin and fibrinogen degradation products, stored and lyophilized in a matrix containing buffer and bulking material. The FDP-values of the FDP Clear Calibrators are specifically assigned for each new lot manufactured. Refer to label on the vials for the lot-specific FDP-values.

MRX1207	1*1 mL FDP Clear Calibrator 1
	1*1 mL FDP Clear Calibrator 2
	1*1 mL FDP Clear Calibrator 3
	1*1 mL FDP Clear Calibrator 4
	1*1 mL FDP Clear Calibrator 5

PRECAUTIONS

Only for *in vitro* diagnostic use. MRX1207 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 (< 1 %). 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 equivalent¹. Replace the stopper and keep the calibrator at 15-25 °C for 5 minutes. 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 15 – 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 FDP Clear 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

MRX132: MRX FDP 550 nm
 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.

LIMITATIONS

This product is designed for calibration of MRX FDP 550 nm reagent. The FDP Clear Calibrator 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 FDP Clear calibrator is assayed and assigned against an in-house reference as standard.

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