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IVD

CE

MediRox

Instructions for Use [EN]

MRX FDP Clear High Control

REF K5019

For *In vitro* Diagnostic Use.

1 Intended use

For quality control of the MRX Green FDP assay. Intended to be used by professional laboratory personnel using coagulation analysers.

2 Background and principle of method

For background information and principle of the method, refer to the Instructions for Use associated with MRX Green FDP (K5016).

3 Components

MRX FDP Clear High Control consists of:
10 × 1 mL lyophilised solution containing human-derived fibrin and fibrinogen degradation products, buffer, bulking material (bovine origin), and preservatives.

4 Metrological traceability

Each new lot of MRX FDP Clear High Control is assigned with MRX Green FDP against in-house reference material with traceability to a working calibrator assigned according to ISO 17511:2003, section 5.6.[1] Refer to the Certificate of Analysis for the lot-specific FDP concentration.

Specification:

Analyte	Specification
FDP	20 - 40 µg/mL

5 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 control 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 potentially infectious.

The control contains 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.

6 Preparation

- Before opening, carefully tap the vial against a surface to collect the lyophilised material at the bottom.
- Add 1.00 mL deionised water (e.g. MRX Laboratory Water, K5036). The water temperature should be 15 - 25 °C.
- Reseal the vial and let it stand for approximately 5 minutes at 15 - 25 °C.
- Gently mix by swirling or rotating until the content is completely reconstituted.

7 Storage and stability

Store at 2 - 8 °C. After reconstitution, stable for 24 hours at 2 - 25 °C in the closed original vial, provided no contamination occurs.

8 Specimen collection and preparation

For specimen collection and preparation, refer to the Instructions for Use associated with MRX Green FDP (K5016).

9 Procedure

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

10 Material required but not provided

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

Reagent	REF
MRX Green FDP	K5016

Control material	REF
MRX FDP Clear Low Control	K5018

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

11 Quality control

To maintain consistent assay results, it is recommended that control plasmas are assayed at regular intervals. MRX FDP 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.

12 Results

The results are reported in µg/mL FDP.

13 Expected values

For expected values, refer to the Instructions for Use associated with MRX Green FDP (K5016).

14 Limitations and interfering substances

For limitations and interfering substances, refer to the Instructions for Use associated with MRX Green FDP (K5016).

15 Analytical performance characteristics

For analytical performance characteristics, refer to the Instructions for Use associated with MRX Green FDP (K5016).

16 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.

17 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.

18 References

1. EN ISO 17511:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

19 Definition of symbols

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

20 Revision history

Version	Changes to previous version
8.0	The device has been CE marked. New IFU design. As a result, all sections have been updated.